

Delivery room routines and initial  
assessment and treatment for infants born  
at 32 to 35 weeks of gestation

A multicentre pilot study comparing three  
different hospitals

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Master Thesis in Health Science

June 2011

## Summary

**Objective:** To compare routines and results regarding immediate postnatal treatment of preterm infants between three hospitals prior to the introduction of Kangaroo Care in the delivery room in order to ensure comparable baseline data for a study group and a control group for a future study. To compare infants delivered vaginally with infants delivered by caesarean section.

**Methods:** This was a descriptive multicentre pilot study using retrospective data from medical records at St. Olavs Hospital, Vestfold Hospital and University Hospital of North Norway. Inclusion criteria were infants born at 32 to 35 weeks of gestation in a stable condition right after birth. Primary outcomes were hypoglycaemia, hypothermia and feeding routines.

**Results:** A total of 63 preterm infants were included. The incidences of the primary outcomes were comparable between the infants delivered vaginally, but not between those delivered vaginally and those delivered by caesarean section. Procedures regarding feeding and blood glucose measurements were different in different hospitals, but not significant.

**Conclusion:** The pilot study was helpful in discriminating between infants eligible for a future study where infants using Kangaroo Care will be compared to infants immediately transferred to an NICU after delivery. The data also revealed procedures that need to be revised. These are important adjustments that may influence the success of the future study.

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Keywords: Kangaroo Care, KMC, KC, preterm, infant, hypothermia, hypoglycaemia

## Relevance

As far as I know, St. Olavs Hospital is the first hospital in Norway where Kangaroo Care (skin-to-skin) for preterm infants is practiced immediately after birth in the delivery room, and thus prevents separation between mother and infant. The present pilot study is the first part of a three part multicentre study that forms the basis for further research on the safety of using Kangaroo Care instead of traditional care in preterm infants immediately after delivery. This retrospective pilot study gives valuable information in front of the prospective future study, and is decisive if the prospective study is feasible.

## Preface

This is my master thesis in Health Science at the Norwegian University of Science and Technology (NTNU). The study was supported by grants from St. Olavs Hospital and Sør - Trøndelag University College, Faculty of Nursing.

First I would like to thank my marvelous supervisors Eva Tegnander and Ragnhild Støen for their fantastic support, words of encouragement and constructive feedback.

I would also like to thank my collaborators Linda Frances Hansen, Randi Mobrårthen and Kirsten Holltrø at Vestfold Hospital, and Janne Wilhelmsen, Mariaana Kajula and Eva Løhngård at UNN. Without them the thesis work could not have been initiated.

I am very thankful to Kari Gulla and Raija Dahlø at Sør -Trøndelag University College, Faculty of Nursing, for their enthusiasm and believe in this study.

I also want to express gratitude to Pål Romundstad for help and advice regarding statistical issues, and Nancy Lea Eik-Nes for revising the manuscript in an educational way, in addition to her skillful assistance with the English language.

My sincere thanks go to all my friends and colleagues at Neonatal Intensive Care Unit at St. Olavs Hospital who have been involved in this project and made the Master Thesis possible.

Finally, my special thanks go to my dear Bjørn, and my children Marius, Maia and Martin for their endless patience.

Trondheim, June 2011

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Abbreviations:

CPAP – Continuous Positive Airway Pressure

GA- Gestational Age

KMC- Kangaroo Mother Care

KC – Kangaroo Care

LBW- Low Birth Weight; defined as weight below 2500 grams (WHO)

NICU- Neonatal Intensive Care Unit

SGA – Small for Gestational Age

Glossary

Preterm infant: Infant born before 37 weeks of gestation

Moderately preterm: Infant born between 32 and 36<sup>6</sup> weeks of gestation

Gestational age: Age in complete weeks at birth according to prenatal ultrasound

Preeclampsia: A pregnancy related complication leading to various degrees of maternal hypertension, placental insufficiency and growth restriction of the foetus

Jaundice: A common condition in newborns caused by immaturity of the pathways of bilirubin metabolism.

## Background

This Master Thesis in Health Science presents a pilot study that is one part of a larger multicentre study whose aim is to evaluate the introduction of Kangaroo Care for preterm infants in the delivery room. The larger study will compare Kangaroo Care for preterm infants in the delivery room with conventional therapy that usually includes transfer to a Neonatal Intensive Care Unit (NICU) immediately after birth. This pilot study was conducted at the Neonatal Intensive Care Unit at St. Olavs Hospital in Trondheim.

This study was a collaboration between the Neonatal Intensive Care Units and maternity units at St. Olavs Hospital, Trondheim University Hospital (St. Olavs Hospital), Vestfold Hospital Trust (Vestfold Hospital) and University Hospital of North Norway Trust (UNN). A joint venture partner was also Sør-Trøndelag University College, Faculty of Nursing.

The multicentre study consists of three parts; a retrospective pilot study, a prospective study collecting medical information on infants delivered in hospitals with or without routines involving Kangaroo Care in the delivery room, and a survey of parents' experiences in the use of Kangaroo Care in the delivery room. The aims of this pilot study were to compare routines and results regarding preterm infants between the three participating hospitals prior to the introduction of Kangaroo Care in the delivery room, and to compare infants delivered vaginally with infants delivered by caesarean section. The pilot study is presented in this Master Thesis in Health Science.

Part one of this thesis comprises an introduction to the medical issues concerning preterm infants relevant for the study, and the theory and concepts related to the introduction of Kangaroo Care method.

Part two has the design of an article. The methods used and the results from the pilot study are presented followed by an expanded discussion.

## Part 1

### 1.1. Preterm infants

Every year, approximately 20 million low-birth-weight (LBW) infants are born worldwide. Infants with low birth weight often have inadequate prenatal growth, and a majority of these infants are born preterm (1). Preterm delivery is one of the largest direct causes of neonatal mortality and morbidity (2). As LBW is an important cause for neonatal death worldwide, one of the greatest challenges in modern medicine is to prevent this (2-4). Many infants born preterm or with intrauterine growth restriction are born to mothers with preeclampsia, but the aetiology of preterm delivery is often unclear and influenced by genetic and environmental factors (3).

In the Neonatal Intensive Care Unit (NICU) at St. Olavs Hospital in Trondheim, extremely preterm infants are offered intensive care if they are born after gestational age of completed 23 weeks. This lower limit for providing life-supporting treatment is in accordance with the statement from the Norwegian national consensus conference on the treatment of extremely preterm babies in 1999 (5). However, the majority of preterm infants admitted to an NICU are preterm infants with a gestational age between 32 and 35 weeks (6). Annually there are approximately 1200 preterm deliveries in Norway, and approximately 80 of these are born at St. Olavs Hospital (6). The distribution of gestational ages among infants born between week 32 and week 35 shows that approximately 20% are born at 32<sup>0</sup> - 32<sup>6</sup> weeks, 30% at 33<sup>0</sup> - 33<sup>6</sup> weeks and 50% at 34<sup>0</sup> - 34<sup>6</sup> weeks (6).

Moderate preterm infants are immature in many ways, although usually not in need of sophisticated high-intensive medical care. They sometimes need ventilator assistance, and they frequently need support to avoid hypothermia and hypoglycaemia, nutritional support and treatment for jaundice.

## 1.2. Hypoglycaemia

After birth, the prenatally continuous transfer of glucose through the umbilical cord is interrupted. Infants born at term have large energy reserves in the form of glycogen and fat, which have been stored during the third trimester. In addition, term infants have a mature hormonal regulatory system with the capacity to build glucose (gluconeogenesis) to compensate for the lack of food supply during the first days after birth (7, 8). This is in contrast to preterm infants who are at high risk of hypoglycaemia (7). The brain and vital organs of neonates must be provided with sufficient glucose, and the consequences of recurrent episodes of hypoglycaemia may give irreversible brain damage and adverse neurodevelopmental outcomes (9).

In LBW infants and preterm infants, the lowest blood sugar level is usually measured during the first two hours after birth (10, 11), and routines for early feeding and intravenous glucose will affect the incidence of hypoglycaemia. In the present study, the three hospitals had common definitions regarding neonatal hypoglycaemia (12).

Hypoglycaemia was defined as  $<2.0$  mmol/l during the first three days of life, and later as  $<2.6$  mmol/l (12). In international studies, the definition of hypoglycaemia varies within a limited area of reference, from  $<2.0$  mmol/l to  $<2.2$ - $2.5$  mmol/l (11).

The incidence of hypoglycaemia varies in different studies, between 6.8% and 16% in preterm infants, and as high as 73% in small for gestational age preterm infants (9, 13-16). The variation may be due to methodological differences, like different gestational ages, different time for blood glucose measurement and different definition of hypoglycaemia.

## 1.3. Hypothermia

Preterm infants have a combination of several disadvantages which predispose them for heat loss (17). They have a lower amount of fat for heat production and isolation, and smaller glycogen stores than term infants. In addition, they have immature and thin skin which increases water and heat loss, and they have poor vascular control with decreased ability to constrict skin capillaries (17). The World Health Organization (WHO) has developed a practical guide for thermal protection of the newborn, including low birth weight and sick newborns (18). A core body temperature between  $36.0$ - $36.4$  °C is

classified as mild hypothermia, 32.0-35.9 °C as moderate hypothermia and <32 °C as severe hypothermia (18). WHO's advice to prevent heat loss in preterm infants includes a warm delivery room, drying the infant immediately after birth and skin-to-skin contact between mother and child (18).

There are four main reasons for heat loss after birth. One is evaporation, for example cutaneous and respiratory heat loss. Another is radiation, for instance losing heat to a cold surface, or convective heat loss to the surrounding air. The last reason is conduction, which is the transfer of heat to the person in direct contact with the infant (19).

The potential consequences of hypothermia are hypoxia, acidosis, hypoglycaemia and pulmonary haemorrhage (19). In a study of 940 neonates, Nayeri and Nili (20) found a significant association between hypothermia and metabolic acidosis, respiratory distress and jaundice, and concluded that hypothermia increased the incidence of complications. According to Nayeri and Nili, hypothermia at birth, particularly in vulnerable preterm infants, is one of the most important factors for death in newborn infants (20).

In a Cochrane review (17), different interventions to prevent hypothermia in preterm infants were evaluated. Standard care was compared to various interventions. Standard care was defined as providing a warm delivery room with temperature at a minimum of 25 °C, drying the infant immediately after birth, removing wet blanket, pre-warming contact surfaces and use of radiant warmers or incubators. The interventions could be categorised into two groups of intervention. One group had barriers to heat loss (i.e. plastic wraps, bags and membranes), where interventions mainly focused on reducing evaporative heat loss; a second group used external heat sources. The second group included studies where skin-to-skin contact between mother and preterm infants was utilized (17). Compared to the conventional incubator, skin-to-skin contact was more effective in reducing the risk of hypothermia for preterm infants (17).

#### 1.4. Nutrition

Accumulation of nutrients in the foetus occurs in the third trimester (weeks 28 to 40) of pregnancy (21). While a full-term neonate has an energy reserve of 3000 kcal, an



extremely preterm infant at 1000 grams has a reserve of only 110 kcal. (21). The moderately preterm infant is born eight to four weeks early, and consequently the fat and glycogen reserves are poorer than in a neonate at term. Postnatal nutrition is therefore of great importance to achieve optimal growth.

Breast milk is considered beneficial for newborn infants, and WHO has recommended exclusive breastfeeding up to 6 months of age (22). In one metaanalysis, it was suggested that low birth weight infants derived greater benefits from breast milk than did infants with normal weight. Significantly higher levels of cognitive function were found in a breast milk group than in a group given formula, and the difference was more pronounced in LBW infants than in normal weight infants (23). Morales and Schanler reported substantial benefits related to the gastrointestinal maturation and infant host defence when preterm infants were fed with breast milk (24). Vohr et al. showed that a predominantly breast milk diet in an NICU was associated with decreased rates of rehospitalisation because of illness after discharge (25, 26).

Moderate preterm infants with a gestation of 32 weeks are not able to coordinate their sucking, swallowing and breathing properly to breastfeed (27). Although human milk is not necessarily enough to meet the preterm infant's need for proteins, minerals and vitamins, human milk is considered beneficial for these infants as well as term infants (21). In these cases the mothers are encouraged to use a breast pump to help maintain milk production. The preterm infants are then able to utilize their mother's milk through a feeding tube, and the human milk can be fortified with nutrients according to the infants' needs.

In a study from Sweden, the correlation between the preterm infant's age and capability to breastfeed was investigated (25). Exclusive breastfeeding was achieved between 32 and 38 weeks of gestation, with a median of 35 weeks. In this study, the use of the Kangaroo Mother Care method (skin-to-skin) was found to be beneficial both in relation to milk ejection and to the infant's ability to breastfeed (28).

## 1.5. Separation or skin-to-skin

In several cultures, the newborn infants are placed naked on their mother's chest immediately after delivery. Historically, this was necessary for the infant's survival. Since deliveries now take place mainly in hospitals, an increased number of newborn infants are separated from their mothers immediately after delivery, or the infants are dressed before returning to their mother (29). This is unique to the 20<sup>th</sup> century, and is common practice in industrialized societies (29, 30).

At St. Olavs Hospital, infants with a gestational age below 35 gestational weeks are, according to local guidelines, always admitted to the NICU after delivery to provide for special needs and medical care. This leads to separation of the mother and the preterm infant. It has been questioned whether this separation is necessary to meet the medical needs of these infants.

As early as in 1972, Klaus et al. described the disadvantages of separation of mother and child after delivery (31). He observed mother/child pairs in two different study groups where one of the groups had extended contact. The mothers who had extended contact with their children showed greater soothing behaviour, had more eye-to-eye contact and fondling than the mothers in the control group (31). Later, several studies have supported these findings (29, 30, 32, 33).

During the first two hours after birth, the full-term infant starts sucking on the breast (34). Sucking is obviously a congenital skill and was confirmed thirty years ago when de Vries et al., by using ultrasound, described sucking and swallowing movements in foetuses at 13-14 postmenstrual weeks (35). Skin-to-skin contact between mother and infant stimulates the natural release of the hormone oxytocin. The newborn's hand-movement (massage-like hand movements) and suckling are presumed to cause this (36). Oxytocin is a hormone released by the pituitary gland and causes uterine contractions after birth, as well as milk ejection and bonding between mother and the newborn (36). Oxytocin also increases the mother's temperature on the chest, which warms the infant (29).

In a randomized trial of 146 mother/child pairs, Bystrova et al. investigated the consequences of early contact versus separation, and the effects on mother-infant

interaction one year after birth (32). Both skin-to-skin care immediately after delivery, and rooming in at the maternity ward were studied. Mother-infant interaction one year later was videotaped and analyzed with the PCERA-method (The Parent-Child Early Relational Assessment method) (37). The study showed that close contact between mother and infant during the first two hours after birth had positive effects on maternal sensitivity to the infant, infant self-regulation and mutuality during play when the infant was one year old (32).

A Cochrane review addressing the early skin-to-skin contact between mothers and healthy late preterm and full term infants concluded that skin-to-skin contact between mother and infant had beneficial effects related to breastfeeding, body temperature and cardio-respiratory stability in preterm infants (29).

## 1.6. The Kangaroo Care method

A way of practicing skin-to-skin contact is the Kangaroo Care method. Out of necessity, the two paediatricians Rey and Martines developed the kangaroo mother program in 1979 in San Juan de Dios Hospital in Colombia. This was a large hospital with 11000 deliveries annually and the Special Baby Care Unit was overcrowded. Infants shared incubators, and the staff had no possibility of observing oxygen saturation or heart rate (38). As a consequence, they developed the kangaroo mother program, a technique of placing the infant between the mother's breast in an upright, prone position (39). In this position, the infant only got mother's milk in a self-regulatory manner. Infants as immature as 32 weeks were cared for at home using this technique. As no artificial milk was given, mother's milk was supplemented with juice from guava (38).

In the past, the Kangaroo Mother Care has engaged many scientists, and leading experts worldwide have established an Expert Group of International Network on Kangaroo Mother Care (40, 41).

The Kangaroo Method distinguishes between continuous Kangaroo Mother Care and intermittent Kangaroo Care (38). The definition of continuous Kangaroo Mother Care is "Early prolonged, and continuous skin-to-skin contact between a mother and her newborn

low birth-weight infant (<2500 gram) both in hospital and after early discharge, with (ideally) exclusive breastfeeding, and proper follow-up” (40). Intermittent Kangaroo Care is “for short periods once or a few times per day, for a variable number of days” (41). It is the latter version, which is the most common in affluent society with high tech NICUs. Clinical guidelines have been developed to help safe implementation of Kangaroo Care of preterm infants in an NICU (42).

### 1.7. Clinical research

Clinical research is important to generate evidence for decision making, and for improving methods of practice (43). It is also a systematic way of examining clinical conditions and outcomes, and to establish relationships between clinical phenomena (43).

Clinical research is a structured process for exploring connections by investigating facts and theories (43). In clinical research there is a taxonomy related to the quality of evidence (44). First is randomized controlled trials, defined as the “golden standard” (43). Number two is evidence from controlled trials without randomization. The third is cohort or case-control studies, preferably from more than one centre. Number four is evidence from series with or without intervention, and number five includes descriptive studies (44). A descriptive study is defined as a study “concerned with, and designed only to describe the existing distribution of variables, without regard to causal or other hypothesis” (45).

Descriptive studies have a central role in medical research, and these kinds of studies are often the first foray into an area of inquiry (45). According to Grimes, good descriptive research should answer the five following questions: who, what, why, when and where. In addition, descriptive research should answer question number six: so what? (45). Grimes claims that it is mainly two groups in descriptive design (studies); studies that deal with individuals and those that deal with populations (45).

A pilot study is defined as a “version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study” (46). Arnold et al. (47) made distinctions between pilot work, pilot study and pilot trials. Pilot work is research of background to inform a forthcoming

study. The pilot study is a study with a specific methodology, objectives and hypothesis. The last one, the pilot trial, includes randomization, and is a pilot study that can stand alone (47).

Some researchers distinguish between pilot studies and feasibility studies (48). A definition of a feasibility study is “pieces of research done before a main study in order to answer the question ‘Can this study be done?’ ”(46).

Reasons for conducting a pilot study could be several, according to Thabane et al. (49). The reasons may refer to the process, the available resources, the scientific issue and the management perspective. The process is when the feasibility is assessed prior to the main study. One example is calculating the sample size. Challenges regarding resources could occur during the main study, for example whether equipment is available when needed. The scientific issue could be a reason to conduct a pilot study to check whether data from the different sources could be matched. The last is the management perspective which covers the potential data and human management problems (49).

According to Thabane et al. (49), the main focus in a pilot study is the feasibility. A pilot study could be helpful in assessing the feasibility of coordination for multicentre trials. In addition, conducting a pilot study prior to the main study enhances the likelihood of success of the main study and helps avoiding potentially doomed main studies (49). Carfoot et al. experienced the importance of a pilot study when they investigated the effectiveness of skin-to-skin care compared to traditional care related to breast feeding (50). The information from the pilot study identified areas where the protocol had to be amended. They concluded, in the light of the pilot study, that a large study on this subject was feasible (50).

Thabane et al. (49) refer to an African proverb from Ghana that says “You never test the depth of a river with both feet”. The main goal of conducting a pilot study is, accordingly, to assess the feasibility to avoid fatal consequences in the forthcoming main study, which could potentially "drown" the whole research project.

## Part 2

### 2.1. Introduction

Skin-to-skin care, or Kangaroo Care, is commonly used for preterm infants in Neonatal Intensive Care Units (NICUs) in Norway. The goal is to empower the mother and father. This is done by gradually transferring to the parents the skills and responsibilities as the newborn infant's primary caregiver and meeting every emotional and physical need (41). Preterm infants are placed on their mother's or father's chest skin-to-skin. Even infants in intensive care, on mechanical ventilation and with central lines, are believed to benefit from this method of care (40). Despite the knowledge that early skin-to-skin contact may benefit early mother-infant attachment, breastfeeding outcomes and cardio-respiratory stability in full term and late preterm infants (29), this practice has not led to the use of skin-to skin-care in the delivery room for preterm infants.

Klaus et al. and Bystrova et al. describe the positive effects that early contact – immediately after delivery – has on bonding between mother and child (31, 32). Although these are findings in full term and late preterm infants, the results may be transferable to healthy, moderately preterm infants (40-42). Studies from other parts of the world with limited resources have indicated that skin-to-skin contact can also be practiced safely with preterm infants (33, 51, 52). The use of skin-to-skin, or Kangaroo Care, in Neonatal Intensive Care Units has been extensively studied (1, 17, 29, 32, 33, 38, 40-42, 53) and has no apparent negative short or long-term effects (29). However, practising Kangaroo Care method in preterm infants in the delivery room has not been extensively studied.

In April 2007, the NICU and the maternity ward at St. Olavs Hospital in Trondheim introduced the provision of Kangaroo Care method in the delivery room to preterm infants  $\geq 32$  weeks of gestation. Rather than transferring the infant to the NICU immediately following delivery, and consequently separating the parents and the newborn infant, a paediatrician and a trained nurse from the NICU were responsible for the infant in the delivery room. Immediately after birth, the preterm infant was put on the mother's chest, assessed clinically and monitored for oxygen saturation levels, heart rate, respiratory rate

and body temperature. Donor breast milk was given within one hour to prevent hypoglycaemia.

Since St. Olavs Hospital is the first hospital in Norway where the Kangaroo Care method has been introduced as a routine after preterm delivery, we wanted to conduct a study to evaluate the Kangaroo method by comparing it to the conventional care. The medical safety of the Kangaroo Care method after preterm delivery at St. Olavs Hospital will be compared to the conventional care that two cooperating hospitals are practising. Before this study could be undertaken, a pilot study was needed to investigate if the three hospitals were comparable regarding incidences of complications (hypoglycaemia and hypothermia) and feeding routines for preterm infants before the introduction of Kangaroo Care.

**The aims of the present study were:**

To evaluate if the incidences of hypoglycaemia and hypothermia, and routines related to feeding infants born at 32 to 35 weeks of gestation are comparable in the three participating hospitals, and to evaluate if these variables are comparable in infants delivered by caesarean section with those delivered vaginally.

## 2.2. Methods

This multicentre study was a descriptive pilot study and was carried out at the Neonatal Intensive Care Unit at St. Olavs Hospital, Vestfold Hospital and University Hospital of North Norway (UNN) between February 2009 and January 2010.

An informed consent (appendix 1), including information about the study, and a pre-paid reply envelope were sent to the parents. If no reply was received, a second copy of the informed consent was sent, but no further effort was made to contact the parents.

Initially, 86 eligible infants were included. Parents of 49 infants had not consented after the second request, three infants did not meet the criteria for the gestational age, thus, the final study group consisted of 31 infants.

Of 24 potential eligible infants from Vestfold Hospital, four of 21 parents did not consent. One infant was excluded because of caesarean section and three did not meet the criteria for the gestational age. A total number of 15 infants, including three pairs of twins, were included in the study.

From UNN, 35 letters were sent to parents of eligible infants. Thirteen of 35 responded. Twenty-two parents received a second letter, and two parents responded. In total, 17 infants from UNN were recruited, including two pairs of twins.

The included preterm infants had a gestational age between 32<sup>0</sup> – 34<sup>6</sup> weeks and were in a stable condition. They were born between April 2003 and Mars 2007, before the Kangaroo Care method was introduced in any of the hospitals. Neonates with asphyxia or known malformations were excluded.

Data were collected retrospectively from the infants' medical records, and recorded on a registration form (appendix 2). The background variables were gestational age at birth and at discharge from the hospital, gender, birth weight and weight at discharge and number of days of hospitalization. Information was collected regarding primary outcomes, including: hypoglycaemia defined as blood glucose <2.0 mmol/l during the first three days of life and <2.6 mmol/l later; hypothermia defined as core body temperature <36.5 °C, time of first feed, frequency of breastfeeding and use of breast milk at discharge. Information regarding secondary outcomes included: the treatments and interventions provided during the hospitalization period, delivery mode, feeding tube, intravenous glucose, mechanical ventilation, supplemental oxygen, frequency of measured blood glucose during the first 24 hours and age at discharge.

Documentation regarding procedures and guidelines related to hypoglycaemia, hypothermia and nutrition were collected from all three participating hospitals. At St. Olavs Hospital in Trondheim, preterm infants delivered by both caesarean section and vaginal delivery were included, whereas at Vestfold Hospital and UNN, only preterm infants delivered vaginally were included.

The regional committee for medical research ethics approved the study.



**Statistics:**

The statistical analyses were performed using SPSS for windows version 18.0. Due to relatively few observations, we estimated median values and used a nonparametric test (Mann-Whitney U-Test) to test for differences in continuous variables and the Pearsons Chi-Square tests for categorical variables. For the power calculations we used Sample Power, version 2.0, for Windows. The level of significance was set at P value < 0.05 (two sided).

### 2.3. Results

Of the 138 eligible preterm infants, 63 (46%) infants were included in the study. Of those, 31 were from St. Olavs Hospital, 15 from Vestfold Hospital and 17 from UNN. Table 1 shows characteristics of the participating infants from the three hospitals.

Table 1. Characteristics of the infants from the participating hospitals.

	St. Olavs Hospital		Vestfold Hospital	UNN
	Caesarean section	Vaginal delivery	Vaginal delivery	Vaginal delivery
Vaginal delivery, n (%)	-	12 (39)	15 (100)	17 (100)
Caesarean section, n (%)	19 (61)	-	0	0
Gestational age (weeks <sup>days</sup> ), median (range)	34 <sup>0</sup> (32 <sup>0</sup> -34 <sup>4</sup> )	34 <sup>1</sup> (32 <sup>5</sup> -34 <sup>5</sup> )	33 <sup>6</sup> (32 <sup>2</sup> -34 <sup>5</sup> )	34 <sup>1</sup> (32 <sup>5</sup> -34 <sup>6</sup> )
Boys, n (%)	6 (32)	6 (50)	8 (53)	10 (59)
Girls, n (%)	13 (68)	6 (50)	7 (47)	7 (41)
Birth weight (grams), median (range)	2095 (1445-3840)	2390 (1725-3160)	2220 (1675-3370)	2335 (1910-2960)
Feeding tube first 24 hours, n (%)	19 (100)	11 (92)	12 (80)	17 (100)
Intravenous glucose within 24 hours, n (%)	10 (53)	4 (33)	5 (33)	6 (35)
Frequency of measured blood glucose within 24 hours, median (range)	5 (3-12)	4 (3-9)	3 (1-5)	4 (1-7)
Mechanical ventilation, n (%)	1 (5)	1 (8)	1 (7)	1 (6)
Supplemental oxygen, n (%)	3 (16) <sup>1</sup>	3 (25)	7 (47)	2 (12)
Antibiotics, n (%)	8 (42) <sup>1</sup>	4 (33)	6 (40)	6 (35)
Weight at discharge (grams), median (range)	2380 (1740-3670)	2620 (2200-3000)	2385 (1870-3200)	2690 (2220-3390)
Gestational age at discharge (weeks <sup>days</sup> ), median (range)	36 <sup>4</sup> (34 <sup>2</sup> -38 <sup>4</sup> )	37 <sup>2</sup> (34 <sup>6</sup> -38 <sup>3</sup> )	35 <sup>6</sup> (34 <sup>6</sup> -38 <sup>0</sup> )	37 <sup>1</sup> (36 <sup>1</sup> -38 <sup>5</sup> )
Days in hospital, median (range)	18 (5-44)	20 (6-37)	19 (8-37)	21 (9-42)

<sup>1</sup> Information missing about supplemental oxygen for one infant and about antibiotics for another infant born at St. Olavs Hospital.

The median birth weight in the group delivered by caesarean section was lower than in the group delivered vaginally, but there was no significant difference between manner of delivery and birth weight ( $p=0.109$ ). No significant difference was seen in weight at discharge and manner of delivery ( $p=0.327$ ) (Table 1).

Table 2 shows blood glucose and temperature levels. In 26 of 30 (87%) infants at St. Olavs Hospital, the lowest blood glucose was measured on admission. Mode of delivery and hypoglycaemia at admission was statistically significant ( $p < 0.05$ ). At UNN, for 7 of 17 (41%) infants, the lowest blood glucose level was measured at another point of time during the first 24 hours. The mother of one infant at Vestfold Hospital, and two mothers at St. Olavs Hospital, had gestational diabetes.

Table 2. Blood glucose and body temperature level at admission and within 24 hours after birth for the preterm infants at the three hospitals.

	St. Olavs Hospital		Vestfold Hospital	UNN
	Caesarean section	Vaginal delivery	Vaginal delivery	Vaginal delivery
Blood glucose level $<2.0$ mmol/l on admission, n (%)	11 (69) <sup>1</sup>	5 (42)	0 (0)	5 (29)
Blood glucose level $<2.0$ mmol/l during 24 hours after birth, n (%)	11 (69) <sup>1</sup>	6 (50)	0 (0)	6 (35)
Infants with body temperature $<36.5$ °C on admission, n (%)	5 (26)	5 (42)	2 (13)	7 (42)
Infants with body temperature $<36.5$ °C during 24 hours after birth, n (%)	9 (53) <sup>2</sup>	8 (67)	3 (20)	12 (75) <sup>2</sup>

<sup>1</sup> Information about blood glucose level was missing for one infant born at St. Olavs Hospital. <sup>2</sup> Information about lowest body temperature within 24 hours was missing for two infants at St. Olavs Hospital and one at UNN.

In table 3, the timing of the first blood glucose measurement related to when the infant was first fed is presented. At St. Olavs Hospital, one infant received milk 30 minutes before the first blood glucose measurement. At UNN, a majority of infants got milk before the first blood glucose measurement, and for half of these the glucose was measured within an hour after the feed. At Vestfold Hospital, all infants were fed before blood glucose was measured, and the glucose was measured between 45 minutes to three and a half hours after birth.

Table 3. Time of first feed in relation to first blood glucose measurement.

	<b>Milk before first blood glucose n (%)</b>	<b>No milk before first blood glucose n (%)</b>
<b>St. Olavs Hospital</b>	1 (3)	29 (97)
<b>Vestfold Hospital</b>	15 (100)	0 (0)
<b>UNN</b>	10 (59)	7 (41)
<b>Total</b>	26 (42)	36 (58)

The majority of infants received mother's milk at discharge (table 4). At St. Olavs Hospital, one infant was given fortified infant formula at discharge due to poor weight gain. Two hospitals used a combination of mother's milk and formula at discharge (table 4).

Table 4. Nutrition at discharge from the Neonatal Intensive Care Unit

	<b>Mother's milk n (%)</b>	<b>Infant formula n (%)</b>	<b>Fortified infant formula n (%)</b>	<b>Combination mother's milk and formula n (%)</b>
<b>St. Olavs Hospital</b>	27 (87)	1 (3)	1 (3)	2 (7)
<b>Vestfold Hospital</b>	11 (73)	3 (20)	0 (0)	1 (7)
<b>UNN</b>	17 (100)	0 (0)	0 (0)	0 (0)
<b>Total</b>	55 (87)	4 (6)	1 (2)	2 (3)

In table 5, the mode of nutrition at discharge is shown. One infant from St. Olavs Hospital was given mother's milk from a bottle.

Table 5. Mode of nutrition at discharge at the different hospitals

	<b>Breastfed n (%)</b>	<b>Bottle n (%)</b>	<b>Combination breastfed/bottle n (%)</b>
<b>St. Olavs Hospital</b>	26 (84)	4 (13)	1 (3)
<b>Vestfold Hospital</b>	9 (60)	3 (20)	3 (20)
<b>UNN</b>	15 (88)	0 (0)	2 (12)
<b>Total</b>	50 (79)	7 (11)	6 (10)

### Guidelines and equipment at the different hospitals

Only the NICU at Vestfold Hospital had written guidelines for measuring blood glucose after birth. Blood glucose was routinely measured immediately prior to the second meal, and the first meal was given as soon as possible after birth (preferably within half an hour). Neither NICU at UNN, nor St. Olavs Hospital had guidelines for blood glucose measurement.

At NICU St. Olavs Hospital and at UNN, the blood glucose was measured by HemoCue Glucose 201+. Vestfold Hospital used the Accu-Chek sensor.

The routine according to the first meal was different among the hospitals. Vestfold Hospital gave meal soon after birth, while St. Olavs Hospital and UNN waited for a longer time. All three hospitals have a human milk bank. This is a system where the hospital buys surplus milk to provide milk for infants who are not getting enough milk from their mother.

To prevent hypothermia in preterm deliveries, St. Olavs Hospital used the Giraffe Omnibed incubator. The incubator can be used open (as a bed with heating above and beneath the infant) and closed (with warmth and humidity). To prevent heat loss, a cap is often placed on the infant's head. To measure the body temperature, St. Olavs Hospital used Servo plax Digitemp.

At Vestfold Hospital they used a Dräger babytherm bed with heating both above and beneath the infant. The infant also wore a cap on its head. To measure the body temperature, a Terumo digital axillary C202 was used.

At UNN, incubators from Dräger, Isolette and Giraffe Omnibed were used during the study period. The latter was the same used at St. Olavs Hospital. At UNN, they used TechStyle TermoLite caps to prevent heat loss. Terumo Digital Clinical was used to measure body temperature.

## 2.4. Discussion

This study was a pilot study to investigate if three collaborating hospitals had comparable routines for the immediate postnatal treatment of moderately preterm infants. Incidence of hypoglycaemia and hypothermia, and routines for early introduction of enteral feeds for infants born at 32 to 35 weeks of gestation were examined. This group of patients is routinely admitted to a Neonatal Intensive Care Unit after birth, with separation of mother and infant as a consequence.

Kangaroo Care after delivery, similar to what is provided for term infants, has been suggested as an alternative to the immediate transfer to the NICU. As far as we know, little data has been reported on the consequences of practicing Kangaroo Care in the delivery room for this group of preterm infants. A study is planned to evaluate the Kangaroo method by comparing it to the conventional care

The present pilot study also had two functions regarding the feasibility of the planned study. One was to ensure that patients could be recruited according to the study plan, and that the registration forms were suitable to collect the data needed. Another function was to investigate if incidences of medical complications differed, and, if so, if any written guidelines or procedures could explain the differences between the hospitals. A third function was calculate the numbers needed in a prospective study based on the incidence of the different complications in this group of infants. These are all common reasons for carrying out pilot studies (49). A pilot study was considered important also from an ethical point of view. The prospective study and co-studies will involve a large number of participants and staff at the different hospitals. In respect to all those involved, the feasibility of the prospective study had to be evaluated to justify the implementation of the next step in this multicentre study.

The response rate from parents of eligible infants was 46%, with a larger response rate at Vestfold Hospital and UNN than at St. Olavs Hospital. The total response rate was low and is difficult to explain. However, when parents are asked to give consent on behalf of their children they may feel challenged about their loyalty. Unlike research on adults, where the informed consent means exchange of information between patient and researcher, it is more complicated in paediatric research as a third part is involved (54). A disadvantage in

this retrospective study could be the complicated research language used on the informed consent form, making the purpose of the study difficult to understand. This may be one explanation of the low turnout. In order to prevent misunderstanding, both written and oral information would be preferable. This way of giving information to the parents on behalf of their children has been emphasized in a study by Allmark et al. (55).

We assumed that the low turnout would not have decisive importance regarding the results, since consistency of the characteristics tested between the infants from the hospitals were comparable. Because of the limited number of participants, we mostly emphasized the routines at the different hospitals, instead of testing for significance.

Birth weights and gender distribution among vaginally delivered infants were also similar at all three hospitals, indicating that these are comparable and representative groups (Table 1).

In the present study, preterm infants delivered by caesarean section had a significantly higher frequency of hypoglycaemia than preterm infants delivered vaginally. There is reason to believe that when preterm infants are delivered by caesarean section there are underlying causes for this decision, such as preeclampsia and intrauterine growth restriction (3). These conditions may influence the infant's condition right after birth, and affect the treatment the first day of life. Thus, these two groups of infants may have received different treatment. The birth weight was considerably lower in preterm infants delivered by caesarean section compared to those delivered vaginally, despite the same gestational age at birth. This indicates more growth restricted infants in the caesarean group, which is associated with lower energy reserves and hypoglycaemia after birth (7, 21). In this light, infants delivered by caesarean section might be in a different medical condition after birth and should not be compared with those born after a vaginal delivery.

As a result of the pilot study, we found that the preterm infants delivered by caesarean section and preterm infants vaginally delivered were not comparable. Preterm infants delivered by caesarean section at St. Olavs Hospital should thus not be included as a control group in the future study. This is of great importance, as inclusion of the infants delivered by caesarean section may have an effect on the results.

Preterm infants are at high risk of developing hypoglycaemia because of low energy sources (7-11). Blood glucose testing is therefore important during the first hours of life. When analyzing the number of hypoglycaemic preterm infants delivered vaginally only, at St. Olavs Hospital, the results were in conformity with the results from UNN. Vestfold Hospital, on the other hand, had no infants with hypoglycaemia. When investigating the probable cause of this result, the pilot study revealed differences in the management of the feeding procedures. St. Olavs Hospital and UNN followed no written procedures. The blood glucose levels of the infants at St. Olavs Hospital were measured prior to the first meal, while 59% of the infants at UNN were fed prior to the first blood glucose measurement (Table 3). At Vestfold Hospital, they followed a strict procedure including a first meal prior to the first blood glucose measurement, thus avoiding the infants' development of hypoglycaemia. It has been documented that the lowest blood glucose levels are seen within two hours after birth (10, 11). This may explain the high number of hypoglycaemic infants at St. Olavs Hospital and the absence of hypoglycaemic infants at Vestfold Hospital.

While 42% of the preterm infants delivered vaginally at St. Olavs Hospital were hypoglycaemic after birth (Table 2), Altman et al. found hypoglycaemia in only 16% of preterm infants (13). The result was substantially lower than the results from both St. Olavs Hospital and UNN (29%). There may be several explanations. The limited number of participants in our study does not consolidate our results. Also, Altman et al. defined hypoglycaemia as plasma glucose value  $< 2.6$  mmol/l three hours after birth, while in our study hypoglycaemia was defined as blood glucose value  $< 2.0$  mmol/l the two first hours after birth. When we take into account that glucose measured in plasma is approximately 13.5% higher than in whole blood (14), and that minimum glucose level is seen during the first two hours after birth (10, 11), it is difficult to compare the results from our study with the study of Altman et al.

The high incidence of hypoglycaemia (73%) reported in Duvanel's study (9), is interesting, because it gives an impression of the heterogeneity of preterm infants' glucose homeostasis. It illustrates the sensitivity of the blood glucose levels with regard to minor differences in birth weight, weeks of gestation and feeding routines. The different results from our study and the study by Altman et al. may demonstrate the influence of these



factors (13).

Different procedures regarding the first blood glucose measurement and the first meal are confounding factors in the present study and could explain the differences in blood glucose level at admission between the three participating hospitals. As a consequence of this pilot study, the procedures related to the first meal and the first blood glucose measurement will be revised to ensure common practice at all three hospitals. Thus, carrying out a pilot study may in itself lead to improvement of methods of practice. Common procedures will also strengthen the results from the forthcoming study.

Hypothermia in preterm infants is a frequent condition because the infants have decreased fat for heat production and isolation in addition to immature skin which increases water and heat loss (17). Compared to Vestfold Hospital, both St. Olavs Hospital and UNN had a higher frequency of hypothermic infants at admission. Collected data could not explain the reason for this, as the equipment and routines used at admission were quite similar between the units.

While the highest prevalence of hypothermia at admission in this study was 42%, Nayeri and Nili described an incidence of hypothermia in 64% of preterm infants with birth weight 1501-2500 grams (20). The body temperature was measured twenty minutes after birth, and a body temperature less than 36.5 °C was regarded as hypothermia. It is difficult to explain the high incidence in this study without exactly knowing their procedure in maintaining the body temperature right after delivery. The limited number of participants in our study makes it difficult to draw any conclusions on the incidence of hypothermia.

Even if we know there is a connection between hypoglycaemia and hypothermia (19), only two of five preterm infants who were hypothermic at admission were hypoglycaemic. At UNN, only one of seven hypothermic preterm infants was hypoglycaemic. These results are in accordance with a study by Nayeri and Nili in which they failed to find a significant relationship between hypothermia and hypoglycaemia (20). However, it is important to underline that the majority of included infants in our study had mild hypothermia, and the majority had body temperature close to 36.5 °C, which is normal (18). As a consequence, our results lack the severe consequences of extremely low body temperature. This is a

good starting point for the future study, where preterm infants practicing Kangaroo Care right after delivery and those who are immediately transferred to NICU after birth will be compared.

The three hospitals reported an unequal share of hypothermic infants within the first 24 hours after birth. If there were any differences in the routine, for instance skin-to-skin method after birth, it has not been reported on the registration scheme. According to various studies, a way of preventing hypothermia could be use of Kangaroo Care right after delivery or when staying at NICU (1, 18, 40). This has been shown in a randomized controlled trial in which Bergman et al. compared skin-to-skin versus conventional incubator right after birth to preterm infants with birth weight 1200-2199 grams. Despite precautions regarding pre-warmed incubators at 36.0 °C, there was a statistically significant difference between the groups. The skin-to-skin group was less hypothermic than the conventional care group (30). These results support the introduction of Kangaroo Care for preterm infants in the delivery room.

Regarding the use of mother's milk as nutrition, all hospitals had comparable routines. Mother's milk as nutrition was dominant after a brief period with donor milk, before the mother established milk production (Table 4). The routines are in accordance with the results from several studies recommending mother's milk as nutrition to preterm infants (21, 23-26) (Table 5). Each of the three hospitals has been accredited as a "Mother-Child-Friendly Hospital" (56), which means that they have a high focus on successful breastfeeding. This may be one reason for the high frequency of breastfed infants at discharge.

A future study on the safety of Kangaroo Care after delivery for moderately preterm infants has been planned. The main goal of the prospective study is to investigate if the incidence of hypoglycaemia and hypothermia increases by delaying the transfer to the NICU, or if the infants should stay with their mother for up to two hours after birth. To ensure proper observation of the newborn, specialized personnel are present.

Based on the results from the pilot study, calculations on sample size for the future study has been carried out. The incidences of hypoglycaemia and hypothermia were 16% and

29%, respectively. This represents results from Vestfold Hospital and UNN which will serve as a control group in the prospective study. The limited number of participants in the pilot study may make the calculation of sample size difficult. However, as published data support our results, the incidences found in the pilot study were used for sample size calculation (13).

If sample size calculation in the forthcoming main study is based on blood glucose level  $<2$  mmol/l, a sample size of 75 preterm infants in the Kangaroo Care group is needed at St. Olavs Hospitals and 150 in the control group from Vestfold Hospital and UNN. This study will have a power of 90% to yield a statistically significant result. With a sample size of 56 and 112 infants for the two groups, respectively, the study will have a power of 80% to yield a statistically significant result. This computation assumes that the difference in proportions is 0.20 (specifically, 0.16 versus 0.36)

If the calculation is based on body temperature  $<36.5$  °C, a sample size of 75 and 150 infant for the two groups is needed. The study will then have a power of 90% to yield a statistically significant result. With a sample size of 56 and 112 for the two groups, the study will have a power of 80% to yield a statistically significant result. This computation assumes that the difference in proportions is 0.22 (specifically, 0.29 versus 0.51).

As three different hospitals are involved, a pilot study was necessary to ensure comparable routines and baseline data before the prospective study could start. Results from the present pilot study emphasized several shortcomings in the registration scheme that will be improved in front of the future study. The registration scheme will be revised and more accurate information will be obtained regarding exact time for first feed and specific nutritional conditions during stay at NICU.

The need for revising the nutrition procedure for all infants hospitalized at NICUs was highlighted in this pilot study. This procedure will be in accordance to the already existing nutrition procedure at Vestfold Hospital, where infants are given their first meal within one hour after birth and blood glucose levels are measured before the second meal.

## 2.5. Conclusion

This pilot study appears to have important implications regarding the future study, and two main findings were of particular interest. First, we found that preterm infants delivered by caesarean section and preterm infants vaginally delivered were not comparable. There was a significant difference in blood glucose between these groups and incidences of the primary outcomes were not comparable. Preterm infants delivered by caesarean section at St. Olavs Hospital should thus not be included as a control group in the future study. This is of great importance, as inclusion of the infants delivered by caesarean section may affect the results.

Second, between the preterm infants delivered vaginally at the three participating hospitals, the incidence of hypoglycaemia, hypothermia and routines related to feeding in preterm infants are comparable. Preterm infants from Vestfold Hospital and UNN are therefore considered suitable as a control group in the future study.

Another important discovery was the absence of procedure related to first feed and the first blood glucose measurement at St. Olavs Hospital and UNN. The results of this study show the importance of a procedure that focuses on the routine of giving the preterm infant nutrition within a limited period after birth to prevent hypoglycaemia. As a consequence of these findings, a new procedure will be developed and practice changed.

Based on the results from this pilot study, we assume that the forthcoming prospective study is feasible.

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Appendix 1.

## **Forespørsel om deltakelse i forskningsprosjekt**

### **Bakgrunn og hensikt**

Ved St Olavs Hospital i Trondheim har Nyfødt intensiv og Fødeavdelingen siden 2007 tilbudt foreldre å benytte kengurumetoden rett etter fødsel på fødestua når de føder fra 8 til 5 uker før termin. Med kengurumetoden menes hud-mot-hud kontakt mellom mor eller far og det premature barnet, i stedet for at barnet umiddelbart blir overflyttet Nyfødt Intensiv slik som er vanlig praksis de fleste steder. Vi ønsker nå å gjennomføre en sammenlignende studie med fødeavdelinger som ikke benytter kengurumetoden for å finne ut om det er noen forskjell på barna m.h.t. temperaturregulering, kontroll av blodsukker og ernæring/ammning.

Nyfødt intensiv ved Sykehuset i Vestfold og UNN er valgt ut for å representere fødeavdelinger der de premature barna vanligvis flyttes fra fødestua til Nyfødt Intensiv relativt raskt etter fødsel. For å finne ut om de tre avdelingene er sammenlignbare, ønsker vi først å samle informasjon om mottak av denne gruppen premature barn før vi innførte kengurumetoden ved St. Olavs Hospital.

**Vi ønsker derfor tillatelse til å få innsyn i mors fødejournal, samt ditt/deres barns medisinske journal fra fødeavdelingen og Nyfødt Intensiv for å registrere medisinske opplysninger som blodsukker, temperatur og ernæring.**

**Kriteriene for å inkluderes i studien er at ditt/deres barn er født mellom 5-8 uker før termin (svangerskapsuke 32 og 35) før mars 2007.**

**Hva skjer med informasjonen om mor og barn?** Det vil bli registrert medisinske opplysninger om mors fødselsforløp samt medisinske opplysninger om barnet under oppholdet på Fødeavdelingen og Nyfødt Intensiv. Vi ber derfor om tillatelse til innsyn i mors og barns medisinske journal under det aktuelle sykehusoppholdet. Det er kun personer knyttet til prosjektet som har adgang til listen med mors og barns navn. Alle data vil bli behandlet konfidensielt. Innsamlede data vil oppbevares i fem år etter studiens slutt for å ha mulighet til å gjennomføre en etterkontroll av data i forbindelse med publisering. All data anonymiseres senest 5 år etter prosjektslutt Det vil ikke være mulig å identifisere mor/barn i resultatene av studien når disse publiseres. Som foreldre har dere rett til innsyn i de opplysninger som blir registrert så lenge studien pågår. Prosjektslutt er satt til 2011 og resultatene av undersøkelsen vil være klar så raskt det lar seg gjøre etter at de samlede data er analysert, men innen utgangen av 2011.



### **Frivillig deltakelse**

Det er frivillig å delta i studien. Du/dere kan når som helst og uten å oppgi noen grunn trekke ditt/deres samtykke til å delta. Dette vil ikke få konsekvenser for ditt/deres barns videre behandling.

Hvis du har spørsmål om studien, kan du kontakte Ragnhild Støen, Seksjonsoverlege/prosjektleder, Nyfødt intensiv/førsteamanuensis dr. med, tlf: 72574045 /72574777 eller Laila Kristoffersen, Intensivsykepleier/prosjektansvarlig sykepleier, tlf: 72 57 42 67/ 72574777 ved St Olavs Hospital, Universitetssykehuset i Trondheim.

Ved Sykehuset i Vestfold HF kan Alf Meberg, Avdelingsoverlege v/Nyfødt intensiv/1.amanuensis dr.med. tlf: 33342304 eller Heidi Jensen Wataker, Spesialsykepleier tlf: 33342304 kontaktes.

Ved Universitetssykehuset i Nord-Norge kan Per Ivar Kaaresen Seksjonsoverlege/1.amanuensis dr.med. tlf: 77626000 eller Avdelingssykepleier Inger Pauline Landsem tlf: 77626362 kontaktes.

## Kapittel A – Utdypende forklaring av hva studien innebærer

Studien er et samarbeidsprosjekt mellom Fødeavdelingen og Nyfødt Intensiv ved St. Olavs Hospital. Høgskolen i Sør Trøndelag, samt Sykehuset i Vestfold HF og Universitetssykehuset i Nord-Norge. Studien vil inkludere barn født før mars 2007. Inklusjonskriteriene er friske premature født mellom uke 32+0 – 34+6. I denne studien vil vi sammenligne journaldata fra barn som er født ved de tre samarbeidende sykehus. Dette for å se om det er gjennomførbart å bruke Sykehuset i Vestfold og Universitetssykehuset Nord-Norge for å rekruttere pasienter til en kontrollgruppe som tas imot uten kengurumottak. I denne studien vil det undersøkes om prosedyrene ved mottak gjør det mulig å sammenlikne ønskede data.

## Kapittel B – Personvern og forsikring

### *Personvern*

Opplysninger som registreres er barnets alder og navn, samt opplysninger om årsak til fødsel, tidspunkt for mat/mengde mat, blodsukkerverdi, barnets temperatur, om barnet er lagt til brystet. Disse opplysninger vil være kodet. Barnets navn vil kun opptre på en navneliste tilknyttet den aktuelle koden. Studien er godkjent av Regional komité for medisinsk og helsefaglig forskningsetikk, Midt-Norge og Norsk samfunnsvitenskaplig datatjeneste (NSD). St. Olavs Hospital er databehandlings ansvarlig institusjon og analysene av innsamlede data vil gjøres her.

### *Rett til innsyn og sletting av opplysninger*

Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg/ditt barn. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du/dere trekker deg/dere fra studien, kan du/dere kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

*Finansiering:* Studien er delfinansiert gjennom samarbeidsmidler med Høgskolen i Sør Trøndelag (HiST) i tillegg til egen institusjon.

*Forsikring:* Pasientskadeerstatningsordningen.

*Informasjon om utfallet av studien:* Studien vil bli presentert i artikkelform innen utgangen av 2011.

Deltakerne i studien har rett til å få informasjon om utfallet/resultatet av studien. Dersom du ønsker tilsendt brev om utfallet av studien når resultatene foreligger, bes du opplyse om din/deres adresse.

Vennlig hilsen

Ragnhild Støen

Laila Kristoffersen

Seksjonsoverlege/Prosjektleder

Intensivsykepleier/prosjektansvarlig  
sykepleier

### Samtykke til deltakelse i studien

Jeg/vi er villige til å delta i studien og tillater at prosjektet får innsyn i mitt/vårt barns medisinske journal fra fødselen.

-----  
(Dato, signatur, mor)

-----  
(Signatur, far)

Adresse for tilsending av brev om resultat av studien

-----  
(Adresse oppgis bare dersom du ønsker tilsendt brev om resultat av studien når disse foreligger)

Jeg bekrefter å ha gitt informasjon om studien

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(Dato, signatur, sykepleier, Nyfødt intensiv / studiemedarbeider)

|

Appendix 2.

## **Registrering av første døgn i avdeling for premature med 32+0 - 34+6 ukers gestasjonsalder født før mars 2007.**

**En samarbeidsstudie mellom Sykehuset i Vestfold HF, Universitetssykehuset Nord-Norge og St. Olavs Hospital**

### **Innkommststatus:**

Forløst: Sectio  Vaginalt

Kode id:

Født: Dato/tidspunkt:

Gestasjonsalder:

Kjønn:

Fødselsvekt:

Lengde:

Hodeomkrets:

Årsak til fødsel:

Første temperatur etter ankomst NI:

Første blodsukker etter ankomst NI:

### **Ernæring første døgn**

Laveste målte blodsukker første levedøgn: Dato:                      Klokken:                      Verdi:

Ventrikkelsonde: Ja  Nei

Intravenøs ernæring/glukose: Ja  Nei

Hvis ja, når ble PVK lagt inn? Dato/tidspunkt:

Årsak til oppstart av intravenøs glukoseinfusjon? Hypoglykemi  Annet

Hvor ofte er blodsukker målt første døgn? Antall:

Væskevolum første levedøgn?                      ml/kg

Type mat:

Morsmelk                                       Forsterket morsmelk

Morsmelkstillegg                               Forsterket morsmelkstillegg

Bankmelk                                       Forsterket bankmelk

### Spisemåte:

- Amming                       Flaske                       Sonde  
 Kombinasjon amming/flaske                       Kombinasjon sonde/amming  
 Kombinasjon sonde/flaske                       Annet (hva):

### **Temperatur første døgn**

De to laveste målte temperaturer første døgn

1. Klokken:                      Verdi:                      Rektal                       Aksillær   
2. Klokken:                      Verdi:                      Rektal                       Aksillær

### **Under oppholdet på NI**

Operasjoner: Ja  nei  Hvis ja. Hvilken type inngrep:

Respirator: Ja  nei  Varighet av respiratorbehandling:                      døgn

Oksygen: Ja  nei  Varighet av oksygenbehov:                      døgn.

Antibiotika: Ja  nei  Varighet av antibiotikabehandling                      døgn

Nevrologi (Patologisk CUL, kramper) Ja  Nei

### **Ved utreise**

Utreisedato:

Utreisevekt:

Alder ved utreise:

Type mat ved utreise:

- Morsmelk                       Forsterket morsmelk  
 Morsmelkstillegg                       Forsterket morsmelkstillegg  
 Bankmelk                       Forsterket bankmelk

Spisemåte ved utreise:

- Amming                       Flaske                       Sonde  
 Kombinasjon amming/flaske  
 Kombinasjon sonde/amming                       Kombinasjon sonde/flaske

### **Kommentarer**