Study Protocol and Statistical Analysis Plan

THE IMPACT OF POSITIONING ON BOTTLE-FEEDING IN PRETERM INFANTS ≤34 GESTATIONAL AGE. A COMPARATIVE STUDY OF THE SEMI-ELEVATED AND SIDE-LYING POSITION

NCT04773613

Document date: 30.06.2018

Study Protocol

INTRODUCTION

Progress in perinatal care results in the increase of preterm infants survivability. Preterm infants need basic life functions support with nutrition being one of these functions. Prematurely born infants often require gastric tube feeding. Transition from enteral (gastric tube) to oral feeding poses a problem for premature infants with cardiovascular and respiratory stability. Therefore, the transition is conducted gradually, taking into account, i.a. the stability of life functions, the maturation of orofacial area reflexes and the efficiency of articulation apparatus, suction-breathing-swallowing coordination, development of autoregulatory mechanisms which are associated with the ability to maintain the activity level which enables feeding. The 32-34 weeks postmenstrual age is usually the moment when premature infants are most likely to begin oral feeding, usually bottle-feeding (the maternal milk, milk from a milk bank, or modified milk). Later on, most premature infants achieve sufficient level of ability to initiate breast or mixed feeding. Indication of proper and effective operations that are aimed at improving the quality and safety of oral feeding is a challenging issue.

One of significant aspects which may contribute to improvement of quality and safety of oral feeding of premature infants is the optimal feeding position. Feeding positioning applied in prematurely born children includes semielevated (SEP) and side-lying (SLP) positions as well as their modifications.

Lack of complete oral feeding often causes delayed discharge of newborn infants from hospital, which may increase the risk of nosocomial patients' infections as well as increasing the cost of hospitalization. Reduction of the factors that adversely affect the introduction of full, effective and safe oral feeding is a very important element of neonatal care. Unfavourable factors such as: saturation decrease, bradycardia or choking episodes are the causes or symptoms of the newborn's stress which may also add to the stress in parents participating in the feeding process. Stress has an obvious detrimental effect on the development of immature brain, causing neuronal atrophy and changes in the hippocampus functioning as well as affecting the immune and neuroendocrine systems. Stress negatively affects mother's lactation due to stress inhibitive effect on the secretion of hormones responsible for milk production. Safe introduction of oral feeding is one of stress-reducing factors for parents. Increased sense of safety

and comfort, in turn, encourages parents of prematurely born infants to try baby feeding on their own.

PURPOSE

The aim of the study is to compare the advantages of SEP and SLP positioning during bottle-feeding of preterm infants ≤34 weeks gestational age.

METHOD

The study will include forty two neonates (n=42) born ≤34 weeks of gestational age. Four bottle-feeding sessions will be testes in each of the newborn: two in the SEP and two in the SLP. The position for the first study will be randomly assigned, then positioning will be changed after each feeding session. In one day, only two consecutive feeding sessions which will be included to the study in order to minimize fatigability as a disrupting factor. The levels of saturation (SpO_2) and heart rate (HR) will be measured as the parameters indicative of the newborn's physiological stability. The factors determining the qualitative aspects of feeding included the total time of declines of SpO_2 ≤85%, level of the newborn's alertness according to the Neonatal Behavioral Assessment Scale (NBAS), and the occurrence of chocking episodes. The proportion of milk consumed (volume of milk eaten relative to the expected volume) and the duration of the feeding and feeding session will be also recorded.

Each feeding session will be recorded with a video camera. It should be mentioned that participation in the study will not oblige the parents to use any of the positions which will be used during the study and to bottle-feeding. Bottle-feeding will be continued with attempts of the breastfeeding, if only it will be possible.

INCLUSION CRITERIA

- circulatory and respiratory stability;
- readiness for oral feeding according to each child's Speech-Language Pathologist assessment;
- prematurely born infants who were in the process of being transferred from enteral nutrition (or enteral nutrition + parenteral nutrition) to full

oral feeding and were fed orally at least 4- 6 times within twenty-four hours;
- parents gave informed consent to participate their infant in the study.

EXCLUSION CRITERIA

- disorders which could significantly affect the feeding course, such as cleft lip and/or palate, facial paralysis and/or congenital defects of the facial skeleton;
- the presence of detected congenital abnormalities and metabolic diseases; low Apgar score (less than 5 points at the 5th and 10th minute of the measurement);
- administered analgesics, anticonvulsants and sedatives;
- <72 hours from extubation prior the trial;
- parents refusal to participate in the study or when bottle-feeding was not the parental preference.

DETAILS OF POSITIONING IN SLP AND SEP POSITIONS

SLP: Infant placed in a SLP on the researcher's lap. Head of the infant symmetrically placed between the shoulders, supported by the researcher's. Shoulder girdle higher than pelvic girdle, head and back in a straight line – a slight natural bent of the body is allowed. Legs bend at an angle of approx. 90˚ in the natural flexion of the knee and ankle joint. The infant's arms close to the midline (on the bottle of researcher's hands).

SEP: Infant placed in a SLP on the researcher's lap. The head rests on the researcher's hand. Shoulder girdle higher than pelvic girdle, head and back in a straight line at an angle of 40-45˚to the ground – a slight natural bend of the body is allowed. Legs bend at an angle of approx. 90˚ in the natural flexion of the knee and ankle joint. The infant's arms close to the midline (on the bottle of researcher's hands).

The research is approved by the Bioethical Commission of the Polish Mother's Memorial Hospital Research Institute, Łódź, Poland - opinion no. 95/2016.

STUDY DESIGN

The study is designed as as a crossover study - alternate study. It will be a randomized trial. Each infant will be bottle-fed four times: twice in the SEP and twice in the SLP. In each of the study positions 84 feeding sessions will be analyzed (total amount of feeding sessions which will be analyzed will be 168). The position for the first trial will be randomly assigned (random table), then positioning will be changed after each feeding session. The study will include observation of the newborn before, during and after the feeding and the following measurements:

A. 2 minutes before the feeding session: oxygen saturation (SpO_2) level, heart rate (HR) (pulse oximeter data), alertness level
B. 3rd minute of the feeding session: SpO_2, HR, alertness level
C. 10th minute of the feeding session: SpO_2, HR, alertness level, volume of food eaten
D. the end of the feeding session: SpO_2, HR, alertness level, volume of food eaten
E. 10 minutes after the feeding session: SpO_2, HR, alertness level

The declines of SpO_2 ≤85% level, total time of feeding and feeding session, occurrence chocking episodes also will be recorded.

During the study feeding, normal feeding session procedures will be applied: avoidance of excessive stimuli by ensuring calm environment with limited level of light and noise, pauses in the feeding after a series of suckling (interval feeding), manual support within the articulation apparatus to improve lip tightness and/or mandibular function. Stimulation of the suction reflex will be also allowed.

Statistical Analysis Plan

In order to verify hypothesis stated in this research, statistical analysis will be conducted using IBM SPSS v. 25 and Jamovi v1.2.8. Frequency distribution analysis, basic descriptive statistics with Shapiro-Wilk's test for normality of distributions, *t*-tests for independent samples, two-way independent mixed ANOVAs as well as chi-squared tests of independency will be computed.

WHAT WILL BE ANALYZED?

- Differences in changes in blood oxygen saturation due to the position of the baby during feeding
- Heart rate variations due to the position of the baby during feeding
- Differences in the change in baby's activity due to the baby's position during feeding
- The position of the baby during feeding and choking episodes
- Differences in the proportion of the volume of eaten food due to the position of the child during feeding
- Differences in feeding times and feeding sessions due to the position of the baby during feeding
- Differences in the time of saturation decrease to the level of ≤ 85% due to the position of the child during feeding

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