IMPROVING GASTROINTESTINAL FUNCTION IN HIGH-RISK NEWBORNS BY STIMULATION OF THE ENTERIC NERVOUS SYSTEM

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Primary objective: determine whether HAPTOS intervention results in earlier attainment (postnatal days) of full enteral feeding and/or full oral feeding (postmenstrual age) compared to standard care. Secondary objectives: To determine whether Haptos...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal tract disorders congenital
Study type	Interventional

Summary

ID

NL-OMON56466

Source
ToetsingOnline

Brief title
NeoHemoHapt Study

Condition

- Gastrointestinal tract disorders congenital
- Gastrointestinal motility and defaecation conditions
- Appetite and general nutritional disorders

Synonym
feeding difficulties, oral feeding

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Radboudumc - Betaalbaar Beter;samenwerkingsbijdrage Amalia kinderziekenhuis & Nutricia B.V.

Intervention

Keyword: - Autonomic and enteric nervous system, - Feeding difficulties, - High-risk newborns, - Tactile-kinaesthetic and oral sensorimotor stimulation

Outcome measures

Primary outcome

Number of days after birth to achieve full enteral feeding and postmenstrual

age to attain full oral feeding;

Secondary outcome

Gastrointestinal motility, cardiorespiratory stability, oral motor skills,

autonomic regulation evaluated by analysis of heart rate variability and

periodic regulation of periodic breathing in relation to interventions,

postnatal period and gestational age; postnatal growth and morbidities,

mortality, feasibility of HAPTOS intervention, parent participation in care.

Study description

Background summary

Infants born preterm or with congenital diaphragmatic hernia (CDH) are at risk for several long-term unfavourable outcomes that can be related to feeding difficulties from birth onwards. Adverse nutritional outcomes in both patient groups mainly originate from mechanical dysfunction, based on dysmotility. Mechanical function includes suck-swallow coordination, gastrointestinal sphincter tone, gastric emptying and intestinal motility and is regulated by the complex interplay of the autonomic (ANS) and enteric (ENS) nervous system with modulation by the central nervous system (CNS). The intra-uterine environment provides the fetus with developmentally timed sensory exposures

through *touch* that are necessary for development of sensory control and autonomous coordination of bodily functions. Preterm infants miss out this normal maturation, while newborns with CDH may exhibit a delayed maturation probably as a result of the deviant anatomical situation and severe illness during the direct postnatal period. In the postnatal situation both patient groups may be confronted with either *negative* sensory stimulation through exposures such as procedural touch/handling, pain or otherwise a reduction in sensory exposures through avoidance of positive touch in relation to supposed clinical instability. All together this may affect normal development and lead to sensory deprivation and delayed maturation of the nervous regulation and cerebral maturation. Tactile-kinaesthetic and oral sensorimotor stimulation using positive gentle touch have been shown to positively affect cardiorespiratory stability, weight gain, gastro-intestinal performance, and length of stay in hospital for preterm infants. However, these strategies have not been evaluated in high-risk infants. The current study aims at evaluating an intervention programme that provides positive stimuli through touch adapted to the stage of development of the infant with regard to timing, duration and intensity that supports the maturational development of gastrointestinal functionality. (Handling Adapted to Postnatal age with Tactile-kinaesthetic and Oral sensorimotor Stimulation; HAPTOS intervention). We hypothesize that the HAPTOS intervention will improve the postnatal maturation of the autonomous and enteral nervous system and cause improvements in gastrointestinal motility, enteral and oral feeding and cardiorespiratory stability.

Study objective

Primary objective: determine whether HAPTOS intervention results in earlier attainment (postnatal days) of full enteral feeding and/or full oral feeding (postmenstrual age) compared to standard care.

Secondary objectives: To determine whether Haptos-intervention compared to standard care results in different outcomes categorized as I. short term clinical outcome II. Short term cardiorespiratory stability and autonomic regulation III. Long-term growth and wellbeing IV. Long-term neurodevelopment V. Parent participation

Study design

Open randomized clinical trial; multicenter

Intervention

All infants will receive the standard of care according to the institutional protocol, while the intervention group additionally will receive a predefined structured daily set of HAPTOS intervention. Parents in the intervention group will be offered to participate in the stimulation programme. Treatment will be

continued according to randomization if the patient is transferred to a participating hospital or otherwise discontinued.

Study burden and risks

All infants in this study will receive standard care according to the principles of individualized developmental care which currently belongs to (inter-) national guidelines and is regarded as safe. The HAPTOS intervention is non-invasive. All endpoints used in this study can and will be assessed non-invasively within the current standard of care for high-risk infants. The intended intervention of the current study differs only slightly from the current standard of care. Stroking of body parts is often already practised within the concept of developmental care. The current study aims to be an advancement of routine developmental care and therefore we assume that participation will not increase the risk for damage and participants even may benefit from participation because the intervention intends to improve the postnatal maturation of autonomous and enteral nervous system and gastro-intestinal outcomes. This study is group related because the described feeding difficulties is a condition that specifically concerns preterm infants and newborns with CDH.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6500 HB
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6500 HB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

1. Preterm birth at gestational age < 30 weeks days or
2. Diagnosis of congenital diaphragmatic hernia
3. Born at Amalia Children*s Hospital or admitted 1rst day of life
4. Written informed consent of both parents or representatives

Exclusion criteria

1. Preterm infant born at gestational age >= 30 weeks
2. Perinatal Asphyxia; (Apgar score at 5* < 5 and first pH <= 7,0)
3. Congenital diaphragmatic hernia in combination with other major congenital anomalies
4. Major congenital anomalies or birth defects other than congenital diaphragmatic hernia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-06-2024
Enrollment:	180

Type:	Actual

Ethics review

Approved WMO Date:	29-01-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-02-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-04-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-11-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT06057415

Register	ID
CCMO	NL84639.091.23