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The role of early nutrition on the development of very low birth weight newborns

Submission date
03/04/2019

Recruitment status
No longer recruiting

Registration date
12/04/2019

Overall study status
Completed

Last Edited
06/09/2024

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Survival rates of babies born prematurely are increasing, but long-term consequences of pre-term birth may persist throughout life. The ideal growth of a premature newborn is considered to be the same as the intrauterine growth of the fetus. However, a premature infant experiences a high level of stress and inadequate nutrition during the hospitalization period despite recommended high nutrient intake. Morbidity during the early neonatal period has a negative impact on growth and neurodevelopment. Optimization of nutrition should improve long-term outcomes. The aim of this study is to look for reliable nutrition assessment markers and evaluate the role of early nutrition on growth, body composition and neurodevelopmental outcomes.

Who can participate?
Very low birth weight (less than 1500 g) newborns born in the Hospital of Lithuanian University of Health Sciences Kauno klinikos can participate in this study, if both parents sign the informed consent. The infant will participate in the study until 12 months corrected gestational age, i.e. until 12 months starting count from the due date. Newborns with congenital anomalies will not be included.

What does the study involve?
The study is non interventional. All newborns receive the same care and feeding regimens according to their clinical condition. Mother's own milk is analyzed for protein, carbohydrates, fat and calories weekly, intravenous and oral intake is calculated daily. Standard measures, such as weight, length and head circumference is checked weekly as well as detailed measurements of upper arm, thigh circumference, lower leg length and skinfold on 4 sites. Blood specimens for hormones affecting growth and adipose tissue accumulation (1 ml of blood) is drawn at 1, 2, 4, 6, 8 weeks or until discharge. Neurodevelopment will be assessed using standardized scales at 12 months corrected gestational age.

What are the possible benefits and risks of participating?
Since there is no intervention, no particular benefit will be from the enrollment. There is a small

risk of bleeding, infection and short-term pain during the blood draw. Pain relief measures are always applied before blood draw. Also there are very small doses of additional radiation during DXA imaging.

Where is the study run from?
The study is running in the Hospital of Lithuanian University of Health Sciences Kauno klinikos.

When is the study starting and how long is it expected to run for?
May 2018 to September 2024

Who is funding the study?
The study is funded by Hospital of Lithuanian University of Health Sciences Kauno klinikos.

Who is the main contact?
The main contact is doctor Rasa Brinkis, rasa.brinkis@lsmuni.lt

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
BE-2-12

Study information

Scientific Title

The role of early nutrition on metabolic markers and hormones, growth and neurocognitive development of very low birth weight newborns

Acronym
RENHGD

Study objectives
The aim of this study is to determine the relationship between early nutrition (evaluating amounts of parenteral and enteral intakes of protein and calories during hospitalisation period), metabolic markers and hormones (glucose, insulin, IGF-1, IGFBP-3, leptin, ghrelin, adiponectin), growth, body composition, morbidity and neurodevelopmental outcomes among VLBW infants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/02/2018, Kaunas Regional Biomedical Research Ethics Committee (A. Mickevičiaus str. 9, LT-44307 Kaunas (406 room); kaunorbtek@lsmuni.lt; +370 615 81669), ref: BE-2-12

Study design
Observational longitudinal cohort study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Growth and neurodevelopment of very low birth weight (<1500 g) newborns

Interventions
Cord blood sample for glucose, insulin, IGF-1, IGFBP-3, leptin, ghrelin, adiponectin and DNA extraction is drawn after birth of very low birthweight newborns. Daily nutritional data are evaluated, composition of mother's own milk or donor milk is analyzed weekly, general anthropometric measures (weight, length, head circumference) as well as detailed anthropometric measures (mid-upper-arm circumference, mid-thigh circumference, lower leg lenght and 4 site skinfold) are performed weekly. 1 ml of blood at 1, 2, 4, 6 and 8 weeks after birth and 12 months corrected gestational age is drawn for glucose, insulin, IGF-1, IGFBP-3, leptin, ghrelin, adiponectin testing. BUN is a part of routine nutritional screening and these data as well as morbidity such as sepsis, necrotizing enterocolitis, bronchopulmonary dysplasia, retinopathy of prematurity are collected from medical records. At discharge and 12 months corrected gestational age DXA analysis for body composition is performed. At 12 months corrected gestational age neurodevelopment is assessed using Bayley II scale.

Intervention Type
Not Specified

Primary outcome(s)

1. Growth restriction at discharge measured using Fenton growth charts
2. Body composition at discharge measured using DXA analysis.

Key secondary outcome(s))
1. At 12 months corrected gestational age neurodevelopment is assessed using Bayley II scale.

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Very low birth weight newborns (<1500g), both AGA and SGA, born in Kaunas Perinatal centre.
2. Parental consent acquired.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Congenital malformations
2. Posthaemorrhagic hydrocephalus
3. Abdominal surgery resulting in part of the bowel resection

Date of first enrolment
31/05/2018

Date of final enrolment
19/05/2020

Locations

Countries of recruitment
Lithuania

Study participating centre

Hospital of Lithuanian University of Health Sciences Kauno klinikos
Eiveniu 2
Kaunas
Lithuania
50009

Sponsor information

Organisation
Lithuanian University of Health Sciences

ROR
https://ror.org/0069bkg23

Funder(s)

Funder type
University/education

Funder Name
Lithuanian University of Health Sciences

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Rasa Brinkis, e-mail: rasa.brinkis@lsmuni.lt, data will be in MS Excel format, available by July/August 2020, the follow-up data will be available November 2021.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/05/2024	06/09/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		16/04/2024	02/05/2024	No	No