

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

Submission date 03/04/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/04/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/09/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> 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

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 length 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 measure

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

Secondary outcome measures

1. At 12 months corrected gestational age neurodevelopment is assessed using Bayley II scale.

Overall study start date

28/02/2018

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

Age group

Neonate

Sex

Both

Target number of participants

120

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

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50009

Sponsor information

Organisation

Lithuanian University of Health Sciences

Sponsor details

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Sponsor type

University/education

Website

<http://www.lsmuni.lt>

ROR

<https://ror.org/0069bkg23>

Funder(s)

Funder type

University/education

Funder Name

Lithuanian University of Health Sciences

Results and Publications

Publication and dissemination plan

Short term outcomes (i.e. growth during hospitalisation period, dietary intakes and biochemical profiles) are going to be published by the end of 2020 or early 2021, long term outcomes are going to be published in 2022, in a high-impact peer-reviewed journal.

Intention to publish date

31/12/2021

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@lsmunis.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?
Preprint results		16/04/2024	02/05/2024	No	No
Results article		13/05/2024	06/09/2024	Yes	No