A randomised, double-blind, controlled trial to evaluate the effects of a new human milk fortifier on growth and tolerance in preterm infants.

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The primary goal is to demonstrate that weight growth velocity (in g/kg/day) from baseline to study day 21 in preterm infants (gestational age

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON50533

Source
ToetsingOnline

Brief title
Renoir

Condition

- Other condition

Synonym
Preterm infants with very low birth weight (<1500g)

Health condition

vroeggeboorte, laag geboortegewicht

Research involving
Human

Sponsors and support

Primary sponsor: Nutricia Research
Source(s) of monetary or material Support: Nutricia Research

Intervention

Keyword: Growth, Human Milk Fortifier, Preterm infants, Tolerance

Outcome measures

Primary outcome

Weight growth velocity (in g/kg/day) from baseline to study day 21.

Secondary outcome

During the intervention period:

- Growth (length, head circumference and anthropometric Z-scores

- Gastro-intestinal tolerance (stools, data on enteral feeding,

vomiting/regurgitation)

Study description

Background summary

Preterm birth (birth before start of the 37th week of gestation) has long-term adverse consequences for health and neurodevelopment and is a major determinant of neonatal morbidity and mortality.
Every year, an estimated 15 million infants worldwide are born prematurely, and this number is rising. Infants who are both preterm and small for gestational age are at even higher risk of medical complications and death than infants with one of these conditions. These babies have much higher nutrient requirements than term infants.
The preferred nutrition for all infants including preterm infants is human milk; however human milk alone does not sufficiently meet the nutritional needs of preterm infants. Therefore human milk fortifiers (HMF) are usually added to milk for preterm infants.
Recent research suggests positive effects on the growth and development by adding lipids to the feedings for preterm infants and that is why Nutricia has developed an HMF with lipids. The composition of the HMF with lipids, when

added to human milk, complies with the increased nutritional needs of preterm infants with a low birth weight, as recently indicated by experts in the field, and is in line with the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) recommendations for intake of nutrients for preterm infants with a very low birth weight.

Study objective

The primary goal is to demonstrate that weight growth velocity (in g/kg/day) from baseline to study day 21 in preterm infants (gestational age <32 weeks and birth weight <1500 g) receiving the HMF with lipids is non-inferior to those receiving the current commercially available HMF without lipids.

Please note that the intervention is intended to last until study day 21 or longer. The intervention will end when the subject is not in need of HMF anymore (according to local feeding procedures), is discharged to a level II or level I NICU that has not been approved for participation in the study or is discharged home, whichever comes first.

The secondary goals are to compare the effects of the HMF with lipids to the effects of the HMF without lipids in preterm infants (gestational age <32 weeks and birth weight <1500 g) concerning growth and gastro-intestinal tolerance.

Study design

This is a randomised, controlled, double blind, parallel-group, multi-centre, multi-country study.

Intervention

During the intervention phase, HMF is added to the mother's milk/donor milk as per the local feeding protocols. Group 1 receives the test product (HMF with lipids); group 2 receives the control product (HMF without lipids). The intervention will end when the subject is not in need of HMF anymore, is discharged to a level II or level I NICU that has not been approved for participation in the study, or is discharged home, whichever comes first.

Study burden and risks

Burden: Most visits and assessments described in the protocol are part of the standard treatment of this group of premature babies. There are no additional assessments that the child has to undergo for this study, except that in some hospitals, length is measured every 2 weeks as part of standard of care. This will be done weekly for the study in all hospitals.
At the Isala, the follow up visit at 6 months is not standard of care and will be done extra for the study. Also at the Isala, the follow-up visits at 12 and

24 months (including the development test) is not standard of care in children born between 30 and 32 weeks of gestational age, and will also be done extra for the study.

The intervention period lasts at least 21 days. Of the children who received less than 15 days of study product due to circumstances, not all follow-up data is included in the statistical analysis. Collecting follow-up data of subjects that is already known not to be used in the end, should be considered unethical. The FUP visits of 12 and 24 months therefore will not be performed for these children.

Risk: Up to now, no previous studies have been conducted with the HMF with lipids. The composition of the HMF with lipids complies with the guidelines and expert recommendations on the nutritional needs of preterm children and safety. The added lipids are already being used as components in (preterm and term) infant formula, without adverse effects due to these lipids.
However there may be unknown side effects. The safety and tolerance of the product will be closely monitored throughout the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

1. Preterm infants fed own mother*s milk (or donor human milk) in need of a HMF (as decided by the investigator)
2. Gestational age <32 weeks and birth weight <1500 g
3. Receiving enteral feeding
4. Expected to be in need of a HMF for minimally 21 days
5. Written informed consent from custodial parent(s)

Exclusion criteria

1. Any relevant proven or suspected chromosomal anomaly, metabolic disorder, genetic syndrome or congenital central nervous system malformation
2. Presence or history of any gastrointestinal malformation/compromise, including Necrotising enterocolitis (NEC) (defined as Bell*s stage two or higher)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	13-12-2018
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	26-04-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-07-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NCT03315221
CCMO	NL61360.029.17