A randomized, controlled, double-blind parallel group trial to study the effects of an infant formula containing partially hydrolysed proteins on growth and tolerance in healthy term infants

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27338

Source
Nationaal Trial Register

Brief title
HerA

Health condition

growth, weight gain, anthropometry, gastrointestinal comfort, safety, suitability, hydrolysate, intact protein, infant formula

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Growth, measured as weight gain in g/day

Secondary outcome

Anthropometry, including

- Weight (kg)

- Recumbent length (cm and cm/day)

- Head circumference (cm and cm/day)

- BMI

- Z-scores for all the above

Study description

Background summary

Background: Formula containing hydrolysed protein may reduce the risk of developing allergic manifestations during the first months of life when breastfeeding is not possible. Hydrolysed proteins could also positively impact gastrointestinal comfort in infants. From 2022 onwards, the use of protein hydrolysates in infant formulae will be restricted by European legislation; IF&FOF manufactured from protein hydrolysates are only allowed to be placed on the market if their composition corresponds to the requirements of Regulation 2016/127. Those requirements may be updated in order to allow the placing on the market of formula manufactured from protein hydrolysates with a composition different from the one already positively assessed, following a case-by-case evaluation of their safety and suitability by EFSA.

Objective: In this clinical trial, weight gain (primary), anthropometry (secondary) and gastrointestinal comfort (tertiary objective) of infants consuming a hydrolysate-based formula is evaluated in healthy infants and compared to consumption of an intact-protein based formula.

Design: 276 infants are recruited before 28 days of age and will be randomized to either a blinded hydrolysed or control formula. They will be followed up for a total duration of at least 3 months until the age of 17 weeks, during which they will be visited by paediatricians/research assistants monthly to evaluate growth, anthropometry and gastrointestinal comfort.

Study objective

Infants’ growth when consuming hydrolysate-based formula is similar to growth when consuming a control formula with intact protein.

Study design

baseline, 8 weeks of age, 13 weeks of age, 17 weeks of age

Intervention

Provide infants with a hydrolysate-based infant formula

Contacts

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Eligibility criteria

Inclusion criteria

• Full-term infants (born at gestational age ≥37 weeks).
• Healthy birthweight (according to WHO Child Growth Standards): between 2500 and 4200 g, retrieved from medical records
• Boys and girls
• Apparently healthy at birth and screening
• Weight-for-age Z-score (WAZ), weight-for-length (WHZ), and length-for-age (LAZ) Z-scores at screening within the normal range according to WHO Child Growth Standards (i.e. -2 ≤ WAZ,WHZ,LAZ ≤ 2)
• Age at enrolment: ≤28 days of age
• Exclusively formula fed for at least 5 days prior to inclusion
• Exclusively formula fed during the entire intervention period

• Parents agreeing to initiate complementary feeding after finalization of the study
• Being available for follow up until the age of approximately 3.5 months
• Written informed consent from parent(s) and/or legal guardian(s) aged ≥18 years

Exclusion criteria

• Gestational age <37 weeks
• Birth weight <2500 g or >4200 g
• Age at enrolment: >28 days
• Severe acquired or congenital diseases, mental or physical disorders, including cow's milk protein allergy, lactose intolerance and diagnosed medical conditions that are known to affect growth (i.e. GI disorders)
• Illness at screening/inclusion
• Incapability of parents to comply with the study protocol
• Illiterate parents (i.e. not able to read and write in local language)
• Participation in another clinical trial
• Unwillingness to accept the formula supplied by the study as the only formula for their child during study participation
• infants fed a special diet other than standard, non-hydrolysed, cow's or goat's milk based infant formula

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-07-2021
Enrollment:	276
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description

N/A

Ethics review

Positive opinion

Date:	11-06-2021
Application type:	First submission

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
NTR-new	NL9536
Other	Harokopio University, Athens, Greece : 26/15-04-2021

Study results

Summary results

N/A