Suitability of Hydrolyzed Infant Formula Tested

No registrations found.

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

Summary

ID

NL-OMON23582

Source
NTR

Brief title
SHIFT

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

- Weight-for-length

- 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 2021 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 (n=190 in total) and compared to consumption of an intact-protein based formula.

Design: 190 infants are recruited between 55 and 80 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 3 months during which they will visit the 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

measurements will be performed at

- baseline

- baseline +1

- baseline +2

- baseline +3

Intervention

Provide infants with a hydrolysate-based infant formula

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

• Full-term, healthy infants (born at gestational age ≥37 weeks).

• Appropriate for gestational age birthweight
(i.e. 10th centile ≤ Birth weight ≤ 90th centile)

• Boys and girls

• Age at enrolment (baseline measurement): between 55 and 80 days of age

• Exclusively formula fed 2 weeks before inclusion

• Exclusively formula fed during the entire intervention period.

• Parents agreeing to initiate complementary feeding after finalization of the study (endpoint measurements at ~5.5 months of age)

• Being available for follow up until the age of approximately 5.5 months

• Written informed consent

Exclusion criteria

• Gestational age <37 weeks

• Birthweight <10th centile or>90th centile

• Age at enrolment: >2 months/55 days and <2.5 months / 80 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

• Participation in another clinical trial

• Unwillingness to accept the formula supplied by the study as the only formula for their child during study participation

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2018
Enrollment:	190
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-10-2018
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	NL7378
NTR-old	NTR7586
Other	Harokopio University, Athens, Greece : 62/03-07-2018

Study results