Acceptance test for lactose free infant formula

No registrations found.

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

Summary

ID

NL-OMON27347

Source
Nationaal Trial Register

Health condition

Lactose intolerance

Sponsors and support

Primary sponsor: Rafik Hariri University Hospital
Source(s) of monetary or material Support: FrieslandCampina

Intervention

Outcome measures

Primary outcome

Anthropometry: weight, length and head circumference

Secondary outcome

Tolerance: regurgitation, colic, dyschezia, constipation, vomiting

Study description

Background summary

A new lactose free infant formula has been developed. Before introducing the product in the market an acceptance test will be carries out to collect safety data.

Apparently healthy infants will consume the study formula for a period of 8 weeks. Anthropometric data and tolerance information will be collected. The hypothesis is that healthy children consuming this lactose free formula will grow in accordance to WHO standards and will tolerate the formula well.

Study objective

Infants consuming the lactose free formula will grow in accordance to WHO growth standards and >80% will not present any intolerance symptoms

Study design

t=0: baseline visit: anthropometry, inclusion questionnaire, tolerance questionnaire, crying diary

t=4 weeks: 2nd visit: anthropometry, crying diary, tolerance questionnaire

t=8 weeks: 3rd and last visit: anthropometry, crying diary, tolerance questionnaire

Intervention

Consumption of lactose free infant formula for 8 weeks

Contacts

Public
61 Quality Rd
I.M.S. Tan-Khouw
[default] 618818
Singapore
+65 6419 8474
Scientific
61 Quality Rd
I.M.S. Tan-Khouw
[default] 618818
Singapore

+65 6419 8474

Eligibility criteria

Inclusion criteria

Full term infants (both males and females) aged 1-4 months)

Infants who are already consuming exclusively regular infant formula for at least two weeks and who tolerate the formula well

Signed informed consent by parents/legal guardians

Parents/legal guardians having the ability to write and read and having the willingness to fulfil all the details of the protocol

No known cow's milk allergy with infant not parents/ siblings

Exclusion criteria

Exclusively breastfeeding at the time of inclusion

Consuming any food for special medical purposes

Gestational age less than 37 weeks

Birth weight less than 2500 grams

Growth parameters at the time of inclusion not in accordance with WHO standards

Feeding problems

Intolerance to infant formula before entering the study

Study design

Design

Study type: Interventional

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-12-2014
Enrollment:	36
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-11-2014
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	NL4747
NTR-old	NTR4875
Other	: Nutr-MC-LacFree

Study results