A randomised, controlled, double-blind trial to evaluate intestinal tolerance of a renewed anti-reflux formula in infants with regurgitation.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21625

Source
NTR

Brief title
PUP study

Health condition

Infants with regurgitation

Sponsors and support

Primary sponsor: Danone Research – Centre for Specialised Nutrition
Source(s) of monetary or material Support: Danone Research – Centre for Specialised Nutrition

Intervention

Outcome measures

Primary outcome

Occurrence and severity of intestinal tolerance characteristics.

Secondary outcome

Safety and occurrence and severity of regurgitation symptoms.

Study description

Background summary

This study aims to investigate the impact of the renewed recipe compared to the currently marketed anti-reflux infant formula primarily on intestinal tolerance, and in addition on safety and efficacy of regurgitation. The study is designed as an equivalence trial of eight weeks with a run-in period on the control product for washing-out any confounding effects and will be conducted in regurgitating infants that are otherwise healthy.

Study objective

The investigational anti-reflux formula will be equivalent to the currently marketed control anti-reflux formula with regard to intestinal tolerance during eight weeks in infants with regurgitation.

Study design

1. Screening;

2. Baseline;

3. 1-week call;

4. 2-week visit;

5. 4-week visit;

6. 8-week visit.

Intervention

Run-in period of 2 to 4 weeks on control product, followed by 8 weeks randomised on either investigational or control product. The investigational product is a renewed anti-reflux formula; the control product is the currently marketed anti-reflux formula.

Contacts

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Eligibility criteria

Inclusion criteria

1. Healthy term infants (37-42 weeks gestation at birth);

2. Age <= 3 months at screening;

3. >= 3 episodes of regurgitation/day at screening;

4. >= 75% formula feeding;

5. Parent's written informed consent;

6. Parent's willingness and ability to comply with the protocol requirements.

Exclusion criteria

1. Clinically significant congenital disease including gastroesophageal, respiratory, and neurological disorders, (suspicion of) food allergies, and disease affecting normal growth;

2. Gastrointestinal infection within 4 weeks prior to randomisation;

3. Use within 4 weeks prior to randomisation and/or anticipated use during study of:

A. Probiotics;

B. Prebiotics (except for human milk);

C. Antibiotics;

D. Cisapride, metoclopramide, proton pump inhibitors, H2 receptor antagonists;

E. Anti-reflux formula (except for assigned study product);

F. Locust Bean Gum (e.g. Nutrilon Nutriton);

G. Weaning food including rice flour (restricted only during run-in and first 4-week investigational period);

H. Other investigational products.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-06-2009
Enrollment:	98
Type:	Actual

Ethics review

Positive opinion

Date:	08-06-2009

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	NL1732
NTR-old	NTR1842
Other	Danone Research B.V. : UAR 2 C/A
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A