Carob bean gum and reflux in infants

No registrations found.

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

Summary

ID

NL-OMON20846

Source
Nationaal Trial Register

Health condition

Uncomplicated oesophageal reflux, infants 2-6 months, oesophageal pH monitoring

Sponsors and support

Primary sponsor: Saint Marina Hospital, Varna, Bulgaria
Source(s) of monetary or material Support: FrieslandCampina, Amersfoort, The Netherlands

Intervention

Outcome measures

Primary outcome

Components of 24-h Oesophageal pH Monitoring using a Digitrapper pH-Z ambulatory 24-hour pH and impedance recorder:

• Percent total time pH < 4

• Percent Upright time pH < 4

• Percent Supine time pH < 4

• Number of reflux episodes

• Number of reflux episodes ≥ 5 min

• Longest reflux episode (minutes)

• SI (symptom index for reflux)

• SSI (symptom sensitivity index)

• SAP (symptom associated probability)

Secondary outcome

The nuimber of visible refluxes and stool consistency as monitored by the parent using a 3-days diary.

Study description

Background summary

Uncomplicated gastro-esophageal reflux (GER) is a common problem affecting about 50% of all babies. Recovery may take more than two years, but the majority will do so within the first year of life. Because of the loss of nutrients due to reflux, GER may result in weight loss. Furthermore, the acidic refluxes may irritate the (lower part of) the esophagus. This means that any early reduction in the number of refluxes, including low-esophageal refluxes, is beneficial for the infant. Thickening the infant formulae with carob bean gum has shown to be succesful. Some evidence is available that carob bean gum is also effective at lower dose with regard to the number of visible refluxes. A lower dose also means a reduced impact on stool consistency. However, no information is available on the number of low-esopageal (invisible) refluxes. For that reason this study has been designed. In term born infants with an questionnaire indicated reflux (I-GERQ>7), two different concentrations (0.45 and 0.33 g/100ml infant formulae) of galactomannans (active part of carob bean gum) will be tested.

Study objective

A lower amount of cold soluble galactomannans (0.33g per 100ml) is as effective as 0.45g/100ml of hot soluble galactomannans in reducing the number of visible and invisible refluxes.

Study design

At study entry (day 0), recruited infants will be provided with a standard infant formula . After 7±2 days a baseline 18-24 hours pH monitoring will be performed. Following the baseline pH

monitoring, infants will be fed in prone-reversed position with the allocated study formula. After 21±2 days (14 days of intervention), the 2nd and final pH-monitoring will take place. Just before baseline pH monitoring and at the end of the intervention period just before the final pH monitoring parents will fill in a 3-days questionnaire on episodes of visible regurgitation, crying, stool characteristics (consistency, colour, and frequency of defecation).

At entry of the study, at baseline measurement and at the end of the study the researcher will measure weight, height and head circumference of the infants.

Intervention

The included infants will be, based on study entry number, at random allocated to one of three study infant formulae. These products have the same basic composition, but differ in amount and type (hot or cold soluble) of galactomannans, whereas products with cold soluble galactomannans also contain small amounts of hydrolysed protein. The intervention will last for 14 days.

Contacts

Public
P.O.Box 226
Anne Schaafsma
Leeuwarden 8901 MA
The Netherlands
+31 (0)58 2992424
Scientific
P.O.Box 226
Anne Schaafsma
Leeuwarden 8901 MA
The Netherlands
+31 (0)58 2992424

Eligibility criteria

Inclusion criteria

1) 2-6 months of age with a score of I-GERQ more than 7, as defined by Orenstein.

2) Proven acid or non-acid reflux with pH-Z ambulatory 24-hour pH and impedance recorder

3) The signed informed consent by one/both parents / legal guardian

4) Available throughout the study period

5) Parents/guardian have the mental ability to understand and willingness to fulfil all the details of the protocol

Exclusion criteria

1) Preferred no breastfeeding at time of inclusion. When the inclusion of participants in not possible because of this criteria, 25% breast milk of total daily milk intake is allowed.

2) Cow’s milk protein allergy diagnosed as positive IgE and/or positive prick reactions to cow’s milk and/or eosinophilia in differential blood count,

3) Preterm birth,

4) Infants with a history of wheezing, aspiration pneumonia, apnea.

5) Anemia with hemoglobin less than 90g/l, as checked by finger prick.

6) Gastro-intestinal bleeding, diarrhoea

7) Infants with laryngitis,

8) Urinary tract infection

9) Weight gain for the last month of more than 100 g/week

10) Apparent life threatening events,

11) Neurologic deficits,

12) Infants with a known organic or metabolic cause of reflux,

13) Infants already receiving anti-reflux formulae or medications that can affect gastrointestinal tract motility.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2013
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-12-2013
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	NL4184
NTR-old	NTR4334
Other	FrieslandCampina : Anne Schaafsma
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A