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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.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

# Samenvatting

## Bron

NTR

## Verkorte titel

PUP study

## Aandoening

Infants with regurgitation

## Ondersteuning

| | |
|---|---|
| Primaire sponsor : | Danone Research – Centre for Specialised Nutrition |
| Overige ondersteuning : | Danone Research – Centre for Specialised Nutrition |

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

## Primaire uitkomstmaten

Occurrence and severity of intestinal tolerance characteristics.

# Toelichting onderzoek

## Achtergrond van het onderzoek

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.

## Doel van het onderzoek

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.

## Onderzoeksopzet

1. Screening;

2. Baseline;

3. 1-week call;

4. 2-week visit;

5. 4-week visit;

6. 8-week visit.

## Onderzoeksproduct en/of interventie

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.

# Contactpersonen

## Publiek

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type : | Interventie onderzoek |
| Onderzoeksmodel : | Parallel |
| Toewijzing : | Gerandomiseerd |
| Blindering : | Dubbelblind |
| Controle : | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status : | Werving gestopt |
| (Verwachte) startdatum : | 11-06-2009 |
| Aantal proefpersonen : | 98 |
| Type : | Werkelijke startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum : | 08-06-2009 |
| Soort : | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL1732 |
| NTR-old | NTR1842 |
| Ander register | Danone Research B.V. : UAR 2 C/A |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Resultaten

## Samenvatting resultaten

N/A