# Consumenten Studie Mexico

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The different processing of formulas will have an effect on stool characteristics such as consistency, frequency, amount and colour.

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving gestopt |
| **Type aandoening** | Maagdarmstelseltekenen en -symptomen |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON20559

**Bron**
Nationaal Trial Register

**Verkorte titel**
TBA

### Aandoening

- Maagdarmstelseltekenen en -symptomen

**Aandoening**

NA

**Betreft onderzoek met**
Mensen

### Ondersteuning

**Primaire sponsor:** FrieslandCampina
**Overige ondersteuning:** FrislandCampina

### Onderzoeksproduct en/of interventie

- Overige

**Toelichting**

## Uitkomstmaten

**Primaire uitkomstmaten**

Primary objective: To investigate the effect of Friso formulas on stool characteristics such as consistency, frequency, amount and colour, compared to competitors.

# Toelichting onderzoek

**Achtergrond van het onderzoek**

This is an eight-day cross-sectional clinical trial meant to investigate the effect of currently consumed infant formulas with different composition, on the gut comfort in infants. A total of 400 subjects, will have the following information collected to asses protein digestion and absorption parameters: • Stool characteristics, using the Amsterdam Infant Stool Scale • Crying Diary • Gastrointestinal symptoms, using a Subject Diary and Questionnaire on Infant/Toddler Gastrointestinal symptoms, IGSQ • Socio economic information using a Socio-Economic Status questionnaire • Fecal samples will be collected during the study to allow for future analysis of relevant parameters of protein digestion and absorption. These parameters will be selected based on primary outcomes analysis.

**Doel van het onderzoek**

The different processing of formulas will have an effect on stool characteristics such as consistency, frequency, amount and colour.

**Onderzoeksopzet**

8 days study - data collected each day

**Onderzoeksproduct en/of interventie**

There is no intervention, this is an observational study of infants habitually using different commercially available infant formulas

# Contactpersonen

## Publiek

FrieslandCampina
Carlijn Maasakkers

## Wetenschappelijk

FrieslandCampina
Carlijn Maasakkers

# Deelname eisen

**Leeftijd**
Baby's en peuters (28 dagen - 23 maanden)
Baby's en peuters (28 dagen - 23 maanden)

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

(i) Term infants (gestational age > 37 weeks and < 42 weeks). (ii) Between 1- 4 months of age without weaning food intake. (iii) Birth weight of 2.5 – 4kg. (iv) Exclusively formula fed. (v) Feeding on the current formula at least 3 weeks prior to the study week. (vi) Infant cared for at home by one or two primary caregivers (parents, legal guardians, etc) who can oversee and record all activity related to data collection. (vii) Parents/caregivers agree to offer (or have offered) no additional food (other than water) over the course of the study and 48 hours before initiation of data collection. (viii) Consenting parent/legal guardian > 18 years old. (ix) Reporting parent fluent in Spanish (language of study). (x) Parents/caregivers own a smartphone and have 24-hour internet connection availability. (xi) At least one of the caregivers should be able to check their email accounts using their smartphone, and successfully download the ClaimIt app during the Screening visit.

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

(i) Breastfed within 3 weeks prior to start of study. (ii) Switched formula within 3 weeks prior to start of the study. (iii) Any complimentary feeding. (iv) Weight-for-length (WFL) above 85th or under 5th percentiles at birth. (v) Congenital condition and/or previous or current illness that, according to the medical judgement of the PI, could interfere with study. These include, but are not limited to; GI tract or metabolic diseases that affect the digestion process and/or confort of the subjects. (vi) Known or increased risk of cow’s milk allergy and/ or lactose intolerance (i.e. one of the biological parents and or siblings diagnosed with cow’s milk allergy, asthma, fever, etc.). (vii) Current participation in another survey or clinical trial. (viii) Investigator's uncertainty about the willingness or ability of the /caregivers to comply with

the protocol requirements (eg. Internet availability, use of technology, compliance with study visits, filling in of diaries and waiting until finishing the study to introduce weaning foods, etc). (ix) Use of antibiotics and/or medication that, based on the investigator´s judgement, treats/cause GI symptoms and appetite changes, as well as probiotic and/or prebiotic supplements (other than those found in the formula itself) at the time of screening and/or two weeks prior to the start of the study.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Fase onderzoek: | N.V.T. |
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Niet-gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |
| Doel: | Anders |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 29-11-2019 |
| Aantal proefpersonen: | 400 |
| Type: | Werkelijke startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nee

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# 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 | NL7805 |
| Ander register | CRO: SPRIM Mexico : Friso01 |

# Resultaten

Datum resultaten gemeld: 18-12-2023

Totaal aantal deelnemers: 342

**Datum eerste publicatie onderzoek**
15-12-2023

**URL result**
Naam
BMC Pediatrics
URL