# Suitability of Hydrolyzed Infant Formula Tested

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Infants’ growth when consuming hydrolysate-based formula is similar to growth when consuming a control formula with intact protein.

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

## Samenvatting

### ID

NL-OMON23582

**Bron**
NTR

**Verkorte titel**
SHIFT

**Aandoening**

growth, weight gain, anthropometry, gastrointestinal comfort, safety, suitability, hydrolysate, intact protein, infant formula

### Ondersteuning

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

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Growth, measured as weight gain in g/day

# Toelichting onderzoek

### Achtergrond van het onderzoek

Background: Formula containing hydrolysed protein may reduce the risk of developing allergic manifestations during the first months of life when breastfeeding is not possible. Hydrolysed proteins could also positively impact gastrointestinal comfort in infants. From 2021 onwards, the use of protein hydrolysates in infant formulae will be restricted by European legislation; IF&FOF manufactured from protein hydrolysates are only allowed to be placed on the market if their composition corresponds to the requirements of Regulation 2016/127. Those requirements may be updated in order to allow the placing on the market of formula manufactured from protein hydrolysates with a composition different from the one already positively assessed, following a case-by-case evaluation of their safety and suitability by EFSA.

Objective: In this clinical trial, weight gain (primary), anthropometry (secondary) and gastrointestinal comfort (tertiary objective) of infants consuming a hydrolysate-based formula is evaluated in healthy infants (n=190 in total) and compared to consumption of an intact-protein based formula.

Design: 190 infants are recruited between 55 and 80 days of age and will be randomized to either a blinded hydrolysed or control formula. They will be followed up for a total duration of 3 months during which they will visit the paediatricians/research assistants monthly to evaluate growth, anthropometry and gastrointestinal comfort.

### Doel van het onderzoek

Infants’ growth when consuming hydrolysate-based formula is similar to growth when consuming a control formula with intact protein.

### Onderzoeksopzet

measurements will be performed at

- baseline

- baseline +1

- baseline +2

- baseline +3

**Onderzoeksproduct en/of interventie**

Provide infants with a hydrolysate-based infant formula

# Contactpersonen

## Publiek

## Wetenschappelijk

# Deelname eisen

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

• Full-term, healthy infants (born at gestational age ≥37 weeks).

• Appropriate for gestational age birthweight
(i.e. 10th centile ≤ Birth weight ≤ 90th centile)

• Boys and girls

• Age at enrolment (baseline measurement): between 55 and 80 days of age

• Exclusively formula fed 2 weeks before inclusion

• Exclusively formula fed during the entire intervention period.

• Parents agreeing to initiate complementary feeding after finalization
of the study (endpoint measurements at ~5.5 months of age)

• Being available for follow up until the age of approximately 5.5 months

• Written informed consent

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

• Gestational age <37 weeks

• Birthweight <10th centile or>90th centile

• Age at enrolment: >2 months/55 days and <2.5 months / 80 days

• Severe acquired or congenital diseases, mental or physical disorders including cow’s milk protein allergy, lactose intolerance and diagnosed medical conditions that are known to affect growth (i.e. GI disorders)

• Illness at screening/inclusion

• Incapability of parents to comply with the study protocol

• Participation in another clinical trial

• Unwillingness to accept the formula supplied by the study as the only formula for their child during study participation

# Onderzoeksopzet

## Opzet

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

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-11-2018 |
| Aantal proefpersonen: | 190 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 11-10-2018 |
| 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 | NL7378 |
| NTR-old | NTR7586 |
| Ander register | Harokopio University, Athens, Greece : 62/03-07-2018 |

# Resultaten