# Single arm, open label, multi-centre intervention trial to evaluate the tolerance and acceptability of a high energy, nutrient enriched infant formula.

Published: 18-10-2012
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The objective of this study is to evaluate the tolerance and acceptability of the new formula in infants receiving the current formula.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON36971

**Source**
ToetsingOnline

**Brief title**
SATIN study

### Condition

- Other condition

**Synonym**
failure to thrive, malnutrition

**Health condition**

groeiachterstand, groeivertraging, ontoereikende voedingsinname, verhoogde energiebehoefte

**Research involving**

Human

## Sponsors and support

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

## Intervention

**Keyword:** acceptability, infant formula, tolerance, undernutrition

## Outcome measures

### Primary outcome

The outcome parameters of this study are:

- daily stool frequency

- daily stool consistency

- daily incidence and intensity of gastrointestinal symptoms: vomiting,

regurgitation, abdominal distension, flatulence, diarrhoea and constipation

### Secondary outcome

The safety outcome parameter in this study is the occurrence of (serious)

adverse events

Other outcome parameter are:

- Compliance: daily study formula intake (current and new formula)

- Convenience: a convenience questionnaire for the caretaker or nursing staff

on Day 8.

# Study description

### Background summary

The composition of Danone's high energy, nutrient enriched infant formula has

recently been adapted in line with recent scientific developments. The improved (new) formula has a composition comparable to the current formula, except a few adaptations. For details on these adaptations please see Protocol section 1.2 and Product Information Brochure. Clinical studies have shown that the currently available formula is safe, well tolerated and promotes growth (see Product Information Brochure section 4.7). The same profile is to be expected from the new formula with the slightly altered composition.
The new formula will be launched end of 2012. Infants that are using current Infatrini at time of the launch will be switched to new Infatrini. No issues with regards to tolerance are expected in relation to this switch, however it is considered important by Danone to have descriptive data on tolerance and acceptability of the new formula prior to this launch in order to support the introduction of the new formula on the (international) market, especially considering the vulnerability of the targeted patient group. Results from this study will be used to support the rationale for full strength transition. In case the study does demonstrate any tolerance issues after full strength transition, it will be suggested to switch infants from current to new Infatrini more gradually.

**Study objective**

The objective of this study is to evaluate the tolerance and acceptability of the new formula in infants receiving the current formula.

**Study design**

This is a single arm, open-label, multi-centre intervention study.

**Intervention**

In the intervention period the infants will receive the new formula during 7 days.

**Study burden and risks**

The burden for the subject and parents/ caretakers is limited and the expected risks are low.

The burden consists of:
- completion of a diary during 10 days. In the diary the parents/ caretakers are asked to document daily the stool frequency and consistency, the study formula intake and the absence/ presence of GI symptoms. 1 page in the diary represents 1 day.
- completion of a convenience questionnaire consiting of 3 multiple-choice questions during visit 2.

In order to ensure the lowest burden possible, the protocol contains the option to perform visit 2 at home or per telephone, in case the parents/ caretakers are unable to come to the hospital with their child for visit 2

If adverse side effects do occur after receiving the new formula, these are expected to be mild and acceptable for the subjects.

## Contacts

**Public**
Danone Research - Centre for Specialised Nutrition

Bosrandweg 20
Wageningen 6704 PH
NL
**Scientific**
Danone Research - Centre for Specialised Nutrition

Bosrandweg 20
Wageningen 6704 PH
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Children (2-11 years)

### Inclusion criteria

*Age 0 to 18 months (including 0 and 18 months)
*Currently receiving a high energy, nutrient enriched infant formula for at least 7 days prior to the baseline visit (day -2)
*Expected to require a high energy infant formula for at least 10 days after baseline visit
*Consuming, on average, at least 50% of their energy intake from the study feed

*Either enterally fed (nasogastric tube, gastrostomy, jejunostomy) or orally fed (bottle fed)
*Written informed consent from parents/ guardians that have legal custody of the child
*Parents/ guardians should have good knowledge of Dutch language

### Exclusion criteria

*Infants less than 37 weeks gestation and requiring specific premature formula at the time of study entry
*Children between 12 and 18 months of age and with a body weight > 9kg that use Infatrini as sole source of nutrition
*Proven cow's milk allergy
*Lactose intolerance
*Galactosaemia
*Other medical or dietary contraindication to a polymeric, high energy, nutrient enriched infant formula (eg major hepatic or renal dysfunction)
*BMR vaccination performed within 14 days prior to baseline visit, any other vaccination performed within 48 hours prior to baseline visit or any vaccination planned within 10 days after baseline visit
*Any surgery planned within 10 days after baseline visit
*Investigator's uncertainty about the willingness or ability of the parent/caregiver to comply with the protocol requirements
*Participation in any other studies involving investigational or marketed products concomitantly or within two weeks prior to entry into the study

## Study design

### Design

**Study type:** Interventional

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 15-01-2013 |
| Enrollment: | 20 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 18-10-2012 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 12-12-2012 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 17-12-2012 |
| Application type: | Amendment |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |

# 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 |
|---|---|
| CCMO | NL40611.041.12 |