

# Study to investigate the nutritional efficacy and tolerance of an infant formula with an added synbiotic mixture in infants

<b>Submission date</b> 12/11/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/12/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 19/12/2012	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims:

This study aimed to demonstrate that the new infant formula does not affect growth and infants were tolerant to the new formula.

### Who can participate?

Healthy term babies, aged under 35 days.

### What does the study involve?

Healthy term infants were randomly allocated to receive either the new infant formula or the standard formula for 13 weeks. During this period participants visited the hospital every 4 weeks to measure growth (e.g. weight, length, head circumference) and other factors (e.g. digestive symptoms).

### What are the possible benefits and risks of participating?

All participants will receive one of the study formulas during the course of the study. Based on current knowledge there are no known risks anticipated with participating in the study.

### Where is the study run from?

Hospitals in Germany.

### When is the study starting and how long is it expected to run for?

Recruitment for the study started in April 2005 and ended in May 2007.

### Who is funding the study?

Danone Research Centre for Specialised Nutrition, The Netherlands

### Who is the main contact?

Dr Mieke Roelofs

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# Contact information

## Type(s)

Scientific

## Contact name

Ms Mieke Roelofs

## Contact details

Danone Research B.V.  
Centre for Specialised Nutrition  
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Netherlands  
6704 PH

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

100.008

# Study information

## Scientific Title

Study to investigate the nutritional efficacy and Acceptance/Tolerance characteristics Of an extensively hydrolyzed whey protein formula with added Synbiotics in infants (ATOS)

## Acronym

ATOS

## Study objectives

The effect of the test formula is equal to the effect of the control formula.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethik-Kommission der Medizinischen Fakultät der Ruhr-Universität Bochum, 29 September 2004  
ref: 2406

## Study design

Randomised controlled double-blind trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Screening

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Healthy infants

**Interventions**

Duration of intervention: 13 weeks.

Intervention group: receiving an infant formula with an added symbiotic mixture for 13 weeks.

Control group: receiving an infant formula without an added symbiotic mixture for 13 weeks.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Weight gain over 13 weeks

**Secondary outcome measures**

1. Growth
2. Gastro-intestinal tolerance
3. Atopic symptoms
4. Gut microbiota composition

**Overall study start date**

01/04/2005

**Completion date**

01/05/2007

**Eligibility****Key inclusion criteria**

1. Healthy term infants (gestational age 37- 42 weeks)
2. 0-35 days of age

3. Normal birth weight dependent on gender, and week of delivery
4. Exclusively formula fed
5. Written informed consent by both parents

**Participant type(s)**

Patient

**Age group**

Other

**Sex**

Both

**Target number of participants**

228

**Key exclusion criteria**

1. Infants with the following allergic symptoms:
  - 1.1. Atopic dermatitis prior to inclusion, according to the Hanifin criteria
  - 1.2. Wheezing
2. Previous use of antibiotics and therapeutic blood components by infant prior to inclusion
3. Previous use of antibiotics by the mother during breastfeeding prior to inclusion
4. Infants with congenital abnormality or chromosomal disorder disease (such as cystic fibrosis, tuberculosis, bronchopulmonary dysplasia, tracheomalacia, tracheoesophageal fistula, major congenital heart disease, downs syndrome)
5. Parental history and pre- or perinatal indications for inherited immunodeficiency syndromes.
6. Infants with congenital infections (Group B streptococcal disease, Hepatitis B, Toxoplasmosis, Rubella, herpes, syphilis, Epstein Bar)
7. Infants requiring intubations or mechanical ventilation
8. Infants of mothers with a significant illness or disability

**Date of first enrolment**

01/04/2005

**Date of final enrolment**

01/05/2007

**Locations****Countries of recruitment**

Germany

Netherlands

**Study participating centre**

**Danone Research B.V.**

Wageningen

Netherlands

6704 PH

# Sponsor information

## Organisation

Danone Research B.V. (The Netherlands)

## Sponsor details

Centre for Specialised Nutrition  
Bosrandweg 20  
Wageningen  
Netherlands  
6704 PH

## Sponsor type

Industry

## Website

<http://www.danone.com/>

## ROR

<https://ror.org/01c5aqt35>

# Funder(s)

## Funder type

Industry

## Funder Name

Danone Research B.V. Centre for Specialised Nutrition (The Netherlands)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

