

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

Submission date 12/11/2012	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 19/12/2012	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 19/12/2012	Condition category Nutritional, Metabolic, Endocrine	☐ Individual participant data
		☐ 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

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6704 PH

Additional identifiers

Protocol serial number

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

Study type(s)

Screening

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(s)

Weight gain over 13 weeks

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration