ISRCTN23993517 https://doi.org/10.1186/ISRCTN23993517

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

Registration date
19/12/2012

Overall study status
Completed

Last Edited
19/12/2012

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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
mieke.roelofs@danone.com

Contact information

Type(s)
Scientific

Contact name
Ms Mieke Roelofs

Contact details
Danone Research B.V.
Centre for Specialised Nutrition
Bosrandweg 20
Wageningen
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 Medizinishcen Fakultät der Ruhr-Universität Bochurm, 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, Toxoplasmose, Rubella, herpes, syphillis, 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