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The effect of early nutrition in high-risk infants on allergy prevention during the first 12 months of life

Submission date
14/02/2006

Recruitment status
No longer recruiting

Registration date
14/02/2006

Overall study status
Completed

Last Edited
04/05/2016

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
The effect of early nutrition in high-risk infants on allergy prevention during the first 12 months of life

Acronym

PATCH

Study objectives
It is expected that feeding a new hypoallergenic formula will result in a lower occurrence of Atopic Eczema Dermatitis Syndrome (AEDS) compared to giving a standard formula in infants with a high risk of developing atopic disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from local medical ethics committee

Primary study design
Interventional

Study design
Multicentre randomised double-blind active-controlled parallel-group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Atopic disease

Interventions
Nutritional intervention starting between the age of 0 to 28 days after birth with formula feeding until the age of 26 weeks in a double-blind, randomised, parallel manner. The study will also include a group of exclusively breastfed infants.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Cumulative incidence of AEDS. Diagnosis according to modified Hanifin and Rajka criteria and SCORAD index of 10 or higher.

Key secondary outcome(s)
1. Severity and course of AEDS
2. Gastro-intestinal tract characteristics
3. Faecal microbiota
4. Immunological blood parameters

Completion date
31/07/2008

Eligibility

Key inclusion criteria
1. Newborn infants
2. High risk classification for atopic disease (at lease one of the parents with documented allergic disease)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Premature delivery
2. Twins
3. Neonatal illnesses
4. Significant congenital abnormalities
5. Intake of cow's milk based formula before randomisation

Date of first enrolment
31/01/2006

Date of final enrolment
31/07/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Numico Research B.V.
Wageningen
Netherlands
6700 CA

Sponsor information

Organisation
Numico Research BV (Netherlands)

ROR
https://ror.org/00aj77a24

Funder(s)

Funder type
Industry

Funder Name
Numico Research BV (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2016		Yes	No