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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	Recruitment status	[_] Prospectively registered
14/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/05/2016	Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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 measure
Cumulative incidence of AEDS. Diagnosis according to modified Hanifin and Rajka criteria and SCORAD index of 10 or higher.

Secondary outcome measures
1. Severity and course of AEDS
2. Gastro-intestinal tract characteristics
3. Faecal microbiota
4. Immunological blood parameters

Overall study start date
31/01/2006

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

Age group
Neonate

Sex
Both

Target number of participants
1200

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)

Sponsor details
PO Box 7005
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Sponsor type
Industry

ROR
https://ror.org/00aj77a24

Funder(s)

Funder type
Industry

Funder Name
Numico Research BV (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

Study outputs

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