

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	<input type="checkbox"/> Prospectively registered
Registration date 14/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/05/2016	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

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 least 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