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

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
14/02/2006		Protocol		
<b>Registration date</b> 14/02/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 04/05/2016	Condition category Skin and Connective Tissue Diseases	[] Individual participant data		
U4/U3//U1b	Skin and Connective HSSHE Diseases			

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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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 Wageningen Netherlands 6700 CA

## 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