

Effects of synbiotics in infants with atopic dermatitis

Submission date
20/12/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
20/12/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
05/11/2010

Condition category
Skin and Connective Tissue Diseases

☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr D.A.M. Goossens

Contact details
Numico Research B.V.
P.O. Box 7005
Alkmaar
Netherlands
6700 CA

Additional identifiers

Protocol serial number
n/a

Study information

Scientific Title

Acronym
Synbad

Study objectives

Pre- and probiotics are able to change the composition of the altered intestinal microbiota that is found in allergic patients, indicating beneficial effects of these nutritional components in the prevention and treatment of allergic diseases. The addition of a patented symbiotic mixture of prebiotics and probiotics to a standard infant formula is assumed to improve the clinical symptoms of Atopic Eczema Dermatitis Syndrome (AEDS).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Study design

Multicentre, randomised, double blinded, placebo controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Atopic Eczema Dermatitis Syndrome (AEDS)

Interventions

Infants will receive in a double-blind fashion either standard infant formula or infant formula with added synbiotics, for 12 weeks.

Analyses:

1. Scord
2. Questionnaires on AEDS symptoms
3. Blood collection for safety, immunological and immunological parameters
4. Stool collection for faecal microbiota evaluation

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Prebiotics, probiotics

Primary outcome(s)

Decrease in Scord score after 12 weeks of treatment is more than 25% greater in the active group compared to the placebo group.

Key secondary outcome(s))

1. Immunological parameters
2. Faecal microbiota parameters

3. Quality of life of the parents and parental stress
4. Gastro-intestinal tract characteristics

Completion date

31/12/2006

Eligibility

Key inclusion criteria

1. Infants, between 0 and 7 months of age
2. Fulfilling standard criteria for AEDS

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

0 years

Upper age limit

7 months

Sex

All

Key exclusion criteria

1. Scord score 15
2. Use of anti-histamines or systemic corticosteroids or anti-mycotic drugs
3. Skin disorder other than AEDS

Date of first enrolment

01/09/2005

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Numico Research B.V.

Alkmaar
Netherlands
6700 CA

Sponsor information

Organisation

Numico Research B.V. (The Netherlands)

ROR

<https://ror.org/00aj77a24>

Funder(s)

Funder type

Industry

Funder Name

Numico Research B.V. (The 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	01/05/2010		Yes	No