Effects of synbiotics in infants with atopic dermatitis.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26088

Source
NTR

Brief title
Synbad

Health condition

Atopic Eczema Dermatitis Syndrome

Sponsors and support

Primary sponsor: Numico Research
Wageningen, the Netherlands
Dr. A. Vriesema
(+31) 317-467800
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Decrease in Scorad score after 12 weeks of treatment is >25% greater in the active group compared to the placebo group.

Secondary outcome

Immunological parameters. Faecal microbiota parameters, Quality of Life of the parents and parental stress, gastro-intestinal tract characteristics.

Study description

Background summary

The effect of synbiotics added to a standard infant formula will be evaluated in infants (0-7months of age) on their AEDS symptoms. Infants will receive in a double-blind fashion either standard infant formula or infant formula with added synbiotica, for 12 weeks.

Study objective

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 synbiotic mixture of prebiotics and probiotics to a standard infant formula is assumed to improve the clinical symptoms of AEDS.

Study design

N/A

Intervention

Scorad, questionnaires on AEDS symptoms, Blood collection for safety, immunological and immunological parameters.
Stool collection for faecal microbiota evaluation.

Contacts

Public
D.A.M. Goossens
Alkmaar
The Netherlands
+31 317 467 800 (direct line: +31 317 467 805).
Scientific
D.A.M. Goossens
Alkmaar

The Netherlands
+31 317 467 800 (direct line: +31 317 467 805).

Eligibility criteria

Inclusion criteria

Main criteria:
Term infants, between 0 and 7 months of age, fulfilling standard criteria for AEDS.

Exclusion criteria

Main criteria:
Scorad score < 15,
use of anti-histamines or systemic corticosteroids or anti-mycotic drugs,
Skin disorder other than AEDS.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2005
Enrollment:	90
Type:	Actual

Ethics review

Positive opinion

Date:	23-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL97
NTR-old	NTR128
Other	: N/A
ISRCTN	ISRCTN69085979

Study results

Summary results
N/A