Study to assess the effect of an added Synbiotic mixture on Atopic dermatitis in INfanTs.

No registrations found.

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

Summary

ID

NL-OMON23678

Source
Nationaal Trial Register

Brief title
SAINT

Health condition

Atopic Dermatitis

Sponsors and support

Primary sponsor: This clinical study will be performed within TOP Institute Pharma (project T1-501). Besides Danone Research, also the Academic Medical Center (AMC) Amsterdam, Wilhelmina Children's Hospital (WKZ) Utrecht, VU University Amsterdam, and the Utrecht Institute for Pharmaceutical Sciences (UIPS) will participate in the TOP Institute Pharma project. Danone Research shall take care of the Sponsor responsibilities as defined by ICH-GCP'.
Source(s) of monetary or material Support: This trial is funded by Top Institute Pharma (40%; cash), industry (40%; 1/2 cash, 1/2 in-kind) and Academy (20%; in-kind). There are several partners involved. The industrial partner is Danone Research. The Academice partners are Academic Medical Center (AMC) Amsterdam, Wilhelmina Kinder ziekenhuis (WKZ) Utrecht, VU Universiteit Amsterdam and Utrecht Institute for Pharmaceutical Sciences (UIPS).

Intervention

Outcome measures

Primary outcome

The primary outcome parameter in this study is the change of SCORAD after 4 months of intervention.

Secondary outcome

1. The severity of exacerbations of atopic dermatitis, measured by SCORAD, Adverse Events and concomitant medication;

2. The amount and class of topical steroids used;

3. The severity of asthma-like symptoms and asthma medication use.

Study description

Background summary

In this study the effect of an added synbiotic mixture in infant formula compared to infant formula without a synbiotic mixture will be assessed in children with atopic dermatitis. After screening subjects will be randomly allocated to receive either the infant formula with synbiotics or the infant formula without synbiotics for a period of 16 weeks. During this intervention period parents will be contacted by phone 3 times every 4 weeks to check how the subject is doing. In case of the occurrence of exacerbations of AD in the subjects during the study the parents will be asked to visit the hospital. After the 16 weeks intervention, the parents will visit the hospital for a final check.

Study objective

A positive effect of using test product with respect to the change of SCORAD after 4 months of intervention in subjects with atopic dermatitis.

Study design

Screening (week -2), Baseline (week 0), Phone call 1 (week 4), Phone call 2 (week 8), Phone call 3 (week 12), End of study visit (week 16).

Intervention

Duration of intervention: 4 months.

Intervention group: Receiving an extensively hydrolyzed whey protein based infant formula with a synbiotic mixture (≥ 500ml/day) for a period of 4 months.

Control group: Receiving an extensively hydrolyzed whey protein based infant formula without a synbiotic mixture (≥ 500ml/day) for a period of 4 months.

Contacts

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Eligibility criteria

Inclusion criteria

1. Infants/children with atopic dermatitis;

2. Between 0-8 months of age;

3. Expected daily intake of at least 500ml of the study product;

4. Written informed consent of both parents / legal representative(s).

Exclusion criteria

1. Intolerance for any other component of the study product(s);

2. History of anaphylactic reaction to cow's milk protein, including severe cardiovascular symptoms (shock), severe laryngeal edema, and bronchus obstruction;

3. Use of antihistamines prior to (48 hours) the study;

4. Use of oral steroids prior to (4 weeks) the study;

5. Use of antibiotics or anti-mycotic drugs prior to (4 weeks) the study;

6. History or presence of cardiovascular, gastrointestinal, hepatic, renal or respiratory chronic disease other than allergy;

7. Major congenital abnormalities;

8. Investigator's uncertainty about the willingness or ability of the parents to comply with the protocol requirements.

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):	07-06-2012
Enrollment:	144
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-05-2012
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	NL3279
NTR-old	NTR3447
Other	Top Institute Pharma : SYN.3.C/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Hulshof L, Overbeek SA, Wyllie AL, Chu MLJN, Bogaert D, de Jager W, Knippels LMJ, Sanders EAM, van Aalderen WMC, Garssen J, Van ’t Land B, Sprikkelman AB. Exploring Immune Development in Infants With Moderate to Severe Atopic Dermatitis. Front Immunol., 2018;9:630.