A randomized, double-blind, placebo-controlled intervention study to assess the therapeutic effect of an extensively hydrolyzed infant formula with an added synbiotic mixture in infants with atopic dermatitis.

Published: 29-03-2012
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2.1 Primary study objectiveThe primary objective of this study is to investigate the therapeutic effect of an extensively hydrolyzed protein based infant formula with a synbiotic mixture on the severity of atopic dermatitis in infants.2.2 Secondary...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON39465

Source
ToetsingOnline

Brief title
SAINT

Condition

- Respiratory disorders NEC
- Skin and subcutaneous tissue disorders

Synonym
atopic dermatitis, eczema

Research involving
Human

Sponsors and support

Primary sponsor: Danone Research - Centre for Specialised Nutrition
Source(s) of monetary or material Support: Top Institute Pharma

Intervention

Keyword: dermatitis, infant formula, synbiotics

Outcome measures

Primary outcome

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

months of intervention.

Secondary outcome

Secondary outcome parameters in this study are:

- The severity of exacerbations of atopic dermatitis.

- The amount of topical steroids used.

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

Study description

Background summary

The addition of a synbiotic mixture to a hydrolyzed infant formula could influence symptoms of Atopic Dermatitis positively.

A mixture of prebiotics and probiotics seems to improve the immune system and therefore the skin complaints in infants with Atopic Dermatitis can decrease, it is also possible that less asthma or asthma-like symptoms will occur.

Study objective

2.1 Primary study objective

The primary objective of this study is to investigate the therapeutic effect of an extensively hydrolyzed protein based infant formula with a synbiotic mixture on the severity of atopic dermatitis in infants.

2.2 Secondary study objective(s)
The secondary objective of this study is to investigate the effect of an extensively hydrolyzed protein based infant formula with a synbiotic mixture in infants with atopic dermatitis with regard to asthma-like symptoms and asthma medication use.

Study design

This is a randomized, double-blind, placebo-controlled intervention study.

Intervention

Test product:
Extensively hydrolyzed whey protein based infant formula with a synbiotic mixture.

Reference product:
Extensively hydrolyzed whey protein based infant formula without a synbiotic mixture.

Study burden and risks

Based on the information we have, we don't expect any risks in participation in this clinical trial.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Infants/children with atopic dermatitis
- up to and includig 10 months of age
- Expected daily intake of at least 500ml of the study product

Exclusion criteria

- Intolerance for any other component of the study product(s)
- History of anaphylactic reaction to cow*s milk protein, including severe cardiovascular symptoms (shock), severe laryngeal edema, and bronchus obstruction.
- Use of antihistamines prior to (48 hours) the study.
- Use of oral steroids prior to (4 weeks) the study.
- Use of antibiotics or antimycotic drugs prior to (4 weeks) the study.
- History or presence of cardiovascular, gastrointestinal, hepatic, renal or respiratory chronic disease other than allergy.
- Major congenital abnormalities.
- Investigator's uncertainty about the willingness or ability of the parents to comply with the protocol requirements.

Study design

Design

Study phase:	3
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-08-2012
Enrollment:	144
Type:	Actual

Ethics review

Approved WMO Date:	29-03-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-12-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL39329.018.12

Study results

Results posted: 05-01-2021

Summary results
Trial ended prematurely

First publication
29-03-2018