Beyond conventional treatment of Atopic eczema in infants: Management By specific prObiOtic strains. A double blind placebo-controlled trial.

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To investigate the therapeutic effect of a selected probiotic mixture on the severity of AD in infants aged 0-15 months. The probiotic mixture has been studied in vitro and has proven IL-10 stimulating effects. Therefore it is thought to decrease AD...

Ethical review	Not approved
Status	Will not start
Health condition type	Allergic conditions
Study type	Interventional

Summary

ID

NL-OMON34286

Source
ToetsingOnline

Brief title
the BAMBOO study

Condition

- Allergic conditions
- Epidermal and dermal conditions

Synonym
allergy, atopic dermatitis, eczema

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van Economische Zaken (Food & Nutrition Delta)

Intervention

Keyword: adaptive immunology, atopic dermatitis, infants, probiotics

Outcome measures

Primary outcome

Primary goal: Is there a decrease in severity of atopic dermatitis (AD) in young children by daily supply of a multispecies probiotic mixture?

The primary outcome will be measured by change in the severity of AD by using the SCORAD score.

Secondary outcomes: subjective (parental) change in eczema severity, change in amount of and type of topical steroid use, quality of life during and after intervention (measured by the validated ITQOL questionnaire), amount of respiratory tract infections, use of antibiotics, use of primary care medicine (general practitioner), change of microbiota composition, change in cytokine pattern.

Secondary outcome

-Effects on infant gut microbiota

Analyses will be done by molecular microbiological techniques on feces samples (that will be collected at baseline, and after 1,3 and 6 months after enrollment.

-Effects on the immature immune system

These effects will be measured by analyzing serum IgE and different (Th1/Th2)

cytokines and chemokines

Study description

Background summary

Atopic dermatitis (AD) is a highly prevalent chronic, itching, inflammatory skin disease that often presents in infancy. The disease can be the first manifestation of the so-called atopic march, the natural progression of allergic disorders, with subsequent development of asthma and allergic rhinitis. Approximately 40% of the children with AD will develop asthma later in childhood.
Currently, topical corticosteroids are the mainstay treatment of atopic dermatitis; however, relapses are common and parents often fear possible side-effects, leading to non-compliance. There is increasing evidence that the intestinal microbiota plays an important role in the development of allergic diseases. Modulation of the intestinal microbiota with probiotics, living micro-organisms with immunomodulatory effects, could possibly offer a new way of treatment of allergic disease. Clinical trials investigating the therapeutic effect of probiotics on atopic dermatitis show inconsistent results. A systematic review of all these clinical trials concluded that the probiotic strains studied to date are not an effective treatment for AD; however, other strains might have a greater effect. So, better results can possibly be achieved by using a selected, in vitro proven modulatory probiotic mixture, containing 6 different strains.

Study objective

To investigate the therapeutic effect of a selected probiotic mixture on the severity of AD in infants aged 0-15 months. The probiotic mixture has been studied in vitro and has proven IL-10 stimulating effects. Therefore it is thought to decrease AD severity in these young children.

Study design

Participants will be randomized, using computer-generated block design lists, drawn up by a statistician, with stratification
according to serum IgE, to daily receive either a powder (sachets) with additional probiotics or the same powder (sachets) without probiotics for a period of 12 weeks.
Patients will be enrolled by the investigator (NR) and sequentially assigned a patient number. Powders will be prepared and coded by Wilclove Bio Industries

BV, Amsterdam and dispensed by the pharmacy of St. Antonius Hospital. Both formulas are identical with respect to smell, taste,
texture, color and packaging. The investigators (NR, AV), participant*s own physicians and parents are all blind to the treatment groups. The randomization key will be owned by the hospital*s pharmacy as well as the company that produces the probiotics.

Intervention

One intervention arm, in which participants daily ingest an (in vitro designed and proven effective modulatory) probiotic mixture for a period of 3 months; compared to controls (in the other arm) that receive a placebo.

-Product name: Ecologic ® Panda II
-Probiotic strains: Bifidobacterium breve (W25), Bifidobacterium lactis (ATCC SD 5219 en ATCC SD 5220), Lactobacillus plantarum (W62), Lactobacillus salivarius (W57) and Lactococcus lactis (W19), 1*109 Colony Forming Units/g.
-Composition: rice starch, maltodextrines, potassium chloride, magnesium sulphate, bacterial strains and manganese suphate.

The placebo mixture is similar in aspect, consistency and taste.

Study burden and risks

- The supply of probiotics to young children has been considered as safe in general. All used strains contain the QPS status.
- All children have to endure blood samples twice. The first one is part of the standard 'eczema treatment', while the second one is considered as additional intervention. Nevertheless, the secong blood sample is important because of determination of specific IgE and cyto- and chemokines before and after (probiotic or placebo) intervention.
- Parents have to visit our hospital 4 times during the study, that is usual frequency for children suffering from atopic dermatitis.
- The parents will be asked to update an included dairy weekly. They should report eczema severity, nutrition pattern, periods of illness/infection, medication use, and possible (serious) side effects.

You may also see paragraph 5 (Safety) and 7 (Ethical issues) of the (Dutch) protocol.

Contacts

Public
Sint Antonius Ziekenhuis

Postbus 2500
3430 EM Nieuwegein
Nederland
Scientific
Sint Antonius Ziekenhuis

Postbus 2500
3430 EM Nieuwegein
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

age 0-15 months
atopic dermatitis for at least 2 weeks, with SCORAD score 15-50

Exclusion criteria

class II or higher class topical corticosteroid use, or use of systemic corticosteroids
antibiotic treatment just before enrollment or in the first week of the study
syndromal abnormalities, major medical problems
lack of knowledge of the Dutch language

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:	Will not start
Enrollment:	120
Type:	Anticipated

Ethics review

Not approved

Date:	18-01-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT01230190
CCMO	NL34163.100.10