Effect of synbiotics in infants with atopic dermatitis up to 7 years of life.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20543

Source
Nationaal Trial Register

Brief title
SYNBAD Follow Up Study

Health condition

Asthma & allergies

Sponsors and support

Primary sponsor: Danone Research – Centre for Specialised Nutrition
Source(s) of monetary or material Support: Danone Research – Centre for Specialised Nutrition

Intervention

Outcome measures

Primary outcome

Prevalence of asthma, measured by a lungtest & questionnaires.

Secondary outcome

Allergic manifestations, as diagnosed by a physician or by means of questionnaires

Study description

Background summary

Since atopic dermatitis (AD) is often the starting point of the "allergic march" and children with AD have a 40% chance of developing asthma, it is interesting to explore if certain probiotic strains can bring the allergic march to a halt,and prevent the development of asthma in these children.

The original Synbad Study showed that the infants with AD who received synbiotics have a lower prevalence of asthma-like symptoms and asthma medication use at one-year follow-up than those who received placebo (van der Aa, Allergy 2010 accepted for publication).

Since this study showed a positive effect in preventing asthma like symptoms in infants at high risk for developing asthma later in childhood, this follow-up study is a good opportunity for further exploration of the prevalence of established asthma in the Synbad children up to 7 years of age.

This study is an observational study in which the same groups will be analysed as in the original double blind parallel randomised SYNBAD trial. For the participants, the study will last 58 weeks and consists of 4 hospital visits and 3 phone calls.

Study objective

A positive effect of the study product in preventing asthma like symptoms in infants at high risk for developing asthma later in childhood.

Study design

The study will last 58 weeks and consists of 4 hospital visits and 3 phone calls.

Intervention

Not applicable. This is an observational follow up study that investigates interventions that were done in a previous study.

Contacts

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Eligibility criteria

Inclusion criteria

1. Participation and completion of Synbad study (all PP subjects);

2. Between 5 years and 6 months and 6 years of age;

3. Written informed consent from parents/caregivers/legal representatives.

Exclusion criteria

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

Study design

Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-09-2010
Enrollment:	78
Type:	Actual

Ethics review

Positive opinion

Date:	15-09-2010
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	NL2415
NTR-old	NTR2523
Other	Danone Research : SYN.2.C/A
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A