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

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Primary study objectiveTo investigate the prevalence of asthma in children up to 7 years of age with atopic dermatitis in infancy who received either Nutrilon Pepti with synbiotics or Nutrilon Pepti without synbiotics during 12 weeks in their first...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON34194

Source
ToetsingOnline

Brief title
SYNBAD Follow Up Study

Condition

- Allergic conditions
- Respiratory disorders NEC

Synonym
Asthma and allergies

Research involving
Human

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

Keyword: Asthma, Baby nutrition, Eczema, Synbiotics

Outcome measures

Primary outcome

The primary study parameter of this study is the physician*s diagnosed asthma

and controllability (GINA classification) at the age up to 7 years.

Secondary outcome

- Allergic manifestations: diagnosed by physician or by means of questionnaires

(ISAAC derived), including severity (if available)

- Blood analysis (Ig's, cytokines)

- Fecal parameters (bacterial content, PH)

- Anthropometry

- Molecular pattern recognition by smell prints of exhaled volatile organic

compounds (Electronic Nose®)

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 later in life, 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).

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

Primary study objective
To investigate the prevalence of asthma in children up to 7 years of age with atopic dermatitis in infancy who received either Nutrilon Pepti with synbiotics or Nutrilon Pepti without synbiotics during 12 weeks in their first 7 months of life.

Secondary study objective(s)
To investigate the prevalence of allergic manifestations (atopic dermatitis, allergic rhinitis, allergic conjunctivitis, allergic urticaria and food allergy) in children up to 7 years of age with atopic dermatitis in infancy and who received either Nutrilon Pepti with synbiotics or Nutrilon Pepti without synbiotics during 12 weeks in their first 7 months of life. Furthermore, blood parameters (e.g. Ig*s, cytokines), fecal parameters (e.g. bacterial composition, pH) are determined as well.

Study design

Prospective follow-up study (investigator and laboratory technicians are blinded for treatment groups), following a randomised, controlled, double blind, parallel design.

Study burden and risks

Based on current information, no negative consequences are expected from participating in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Participation to and completion of the Synbad study
- Between 5 years and 6 months and 6 years of age
- 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 invasive
Intervention model:	Other

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-03-2011
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
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	NL33703.018.10