MIPS Follow up - Local continuation of an observational, double-blind, follow up study as an extension of a randomised double-blind controlled study with a parallel group design on the effect of formula feeding (IF?FOF) supplemented with a mixture of immunologically active neutral and acidic oligosaccharides in healthy term born infants during their first year of life (during MIPS1) on the incidence of atopic diseases and infections around their 3rd year of life until the completion of their 7th

Published: 16-04-2013
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Has the supplementation of oligosaccharides in the first year of life an effect on the incidence of atopic diseases and infections from the 5th until the 7th year of life in healthy children

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immune disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON38744

Source

ToetsingOnline

Brief title
MIPS Follow up - Local continuation

Condition

- Immune disorders NEC
- Viral infectious disorders

Synonym
allergy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: eigen onderzoeksgeld verzameld uit eerdere studie

Intervention

Keyword: atopic diseases, infant feeding, oligosaccharides, RCT

Outcome measures

Primary outcome

atopic diseases

infections

biochemical immune parameters

faeces parameters

Secondary outcome

safety: functional gastrointestinal diseases / symptoms

Study description

Background summary

In MIPS1 in a randomised double blind placebo controlled multicenter study to assess the effect of oligosaccharides added to infant formula feeding the incidence of atopic diseases was reduced in the first year of life in healthy term born infamts. There was no reduction in the incidence of fever episodes. Mips 2 (3-5 years of age) no effect was shown (preliminary results)

Study objective

Has the supplementation of oligosaccharides in the first year of life an effect on the incidence of atopic diseases and infections from the 5th until the 7th year of life in healthy children

Study design

Observational follow up study of the Groningen cohort

Study burden and risks

for the participating children the burden is minimal
-physical examination at home visit
-venapuncture (at home visit) in case of separate informed consent

the parents keep a diary and will be called once per half year
a feaces sample is collected at the home visit day

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Participation in MIPS 1 and 2 and informed consent

Exclusion criteria

None

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-03-2013

Enrollment:	125
Type:	Actual

Ethics review

Approved WMO Date:	16-04-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL43524.042.13