

Effect of the addition of pre-biotics to infant formula on markers of immune development and atopy at 5 years of age

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are there differences in levels of IgE and sub-classes, TARC ,light chain IgG and titers against vaccins HiB and Tetanus between children who received as infant a formula with or without pre-biotics ?

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

Summary

ID

NL-OMON35946

Source

ToetsingOnline

Brief title

IM-MIPS

Condition

- Allergic conditions
- Hepatobiliary neoplasms malignant and unspecified

Synonym

allergy, infections

Research involving

Human

Sponsors and support

Primary sponsor: Danone Research

Source(s) of monetary or material Support: Ministerie van OC&W,Danone research

Intervention

Keyword: atopy, immune development, prebiotics

Outcome measures

Primary outcome

levels of IgE and subclasse, TARC, light chain IgG and titers against HiB and tetanus

Secondary outcome

none

Study description

Background summary

infections and allergic manifestations are the most frequent problems in young children. Recent studies in animals as well as in infants with a family history of atopy, indicate that the type of infant formula might influence the development of the immunesystem and thereby the incidence of infections and allergic manifestations. Studies indicate that oligosaccharides or pre-biotics may be one of the components in human milk that might be responsible for the lower incidence in infections and allergic symptoms that can be seen in breastfed infants. In 2005 the MIPS study started in 7 centers in 5 european countries evaluating the potential effect of adding a mixture of pre-biotics to infant formula. In total 1130 infants were included, 414 receiving infant formula with pre-biotics, 416 infants an identical formula without the pre-biotics and 300 breastfed infants as reference group. In 70% of the infants blood was taken at 6 and 12 month for the analysis of markers of allergy and response to vaccinations as marker of immune development. A lower incidence of allergic skin symptoms were seen in the pre-biotic group compared to controls, but no difference in allergic parametrs or vaccination response. This was in contrast to an previous study in children with a family history of atopy where lower levels of IgE and TARC wre found. We now want to evaluate if there are differences in the same immune parameters at 5 years of age.

Study objective

are there differences in levels of IgE and sub-classes, TARC ,light chain IgG and titers against vaccins HiB and Tetanus between children who received as

infant a formula with or without pre-biotics ?

Study design

venapuncture in those infants of the original MIPS cohort of whom the parents agree with the venapuncture

Study burden and risks

only burden is the venapuncture

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Infants who participated in the MIPS-1 study and agreed to participate in the follow-up MIPS-II study

Exclusion criteria

children from whom the parents do not give consent for blood sampling

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2011
Enrollment:	156
Type:	Actual

Ethics review

Approved WMO	
Date:	17-10-2011
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
Other	DRKS00000229
CCMO	NL35569.042.11