The influence of young child formula containing short-chain galactooligosaccharides, long-chain fructooligosaccharides and n-3 long-chain polyunsaturated fatty acids on recurrent upper respiratory tract infections in children: a randomised, controlled trial.

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To evaluate whether YCF with added scGOS/lcFOS and n-3 LCPFUAs can decrease the number of upper respiratory tract infections compared to cow*s milk in children aged 12-36 months with recurrent upper respiratory tract infections.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON47616

Source
ToetsingOnline

Brief title
Growing up milk and recurrent upper respiratory infections in children

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
ailing toddlers, Recurrent upper respiratory tract infections

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Nutricia,Stichting Pediatrisch Onderzoek Enschede

Intervention

Keyword: Children, Nutrition, Upper respiratory tract infections

Outcome measures

Primary outcome

The main study parameter is:

• The total number of episodes of upper respiratory tract infections during the

six month study period.

Secondary outcome

Secondary study parameters are:

- The average number of days a month with symptoms of an upper respiratory

tract infection in the last three months of the study.

- Influence of growing up milk, compared to cow*s milk, on:

• iron status markers; Hb, mean cell volume (MCV), reticulocyte count,

ferritin, soluble transferrin receptor (change from baseline);

• vitamin A, D and C status (change from baseline);

• number of days absence of parents from work and (recorded by parents);

• the number courses of prescribed antibiotics (recorded by parents).

Explorative study parameters are

- Influence of growing up milk, compared to cow*s milk, on:

• levels of immunoglobulins A, G and M in serum and IgA in saliva (change from

baseline);

• serum zinc levels (change from baseline)

Study description

Background summary

Recurrent upper respiratory tract infections are a common problem with a great number of days with illness for young children. At the moment there is no suitable treatment for patients with an idiopathic cause of recurrent upper respiratory tract infections. This can lead to an increased burden in parental concern and productivity, as well as unnecessary prescription of antibiotics. A recent studie suggests a beneficial effect of young child formula (YCF) with added short chain galactooligosacharides, long-chain fructooligosaccharides (scGOS/lcFOS) and n-3 long-chain polyunsaturated fatty acids (n-3 LCPFUAs) on infections in children attending day care. There are no randomised controlled trials yet that have investigated the effects of this product in children with recurrent URTI.

Study objective

To evaluate whether YCF with added scGOS/lcFOS and n-3 LCPFUAs can decrease the number of upper respiratory tract infections compared to cow*s milk in children aged 12-36 months with recurrent upper respiratory tract infections.

Study design

A multicentre, open, randomised controlled trial will be performed

Intervention

Intervention group: 300 ml YCF with added scGOS/lcFOS and n-3 LCPFUAs per day
Control group: 300 ml cow's milk per day

Study burden and risks

The dietary advice is not complex and risk-free. The only burden includes one extra venapunction and time to fill in the diaries. The time investment for the follow-up consults equals to standard care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children between 12-36 months of age.
Recurrent upper respiratory tract infections (>=3 in the last three months).
Familiar with and currently drinking milk products; expected study product intake of 300 ml per day.
Understanding of Dutch language by parents.
Written informed consent.

Exclusion criteria

Immunological deficiencies.
Atopic dermatitis according to the Hannifin criteria.
Known or suspected disorder of intestinal absorption.
Prophylactic use of antibiotics.
Children with allergies or intolerances for lactose, milk protein or fish protein
Disorders requiring a special diet.
Expected or foreseen inability of the subject and/or their families to adhere to protocol
instructions, including daily completion of the diary by the parents
Any relevant congenital abnormality, anatomical abnormality, chromosomal disorder or severe disease.
Current use of growing up milk.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-11-2016
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	12-05-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-08-2019
Application type:	Amendment
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
CCMO	NL56644.044.16
Other	volgt