The influence of a dietary advice consisting of green vegetables, beef and whole dairy products on recurrent upper respiratory tract infections in children, a randomised controlled trial.

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A treatment method of a dietary advice of green vegetables, beef and whole dairy products during twelve months including standard supportive care can decrease the number and duration of upper respiratory tract infections compared to standard...

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

Summary

ID

NL-OMON41864

Source
ToetsingOnline

Brief title
The influence of a dietary advice on recurrent URTI 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: Vakgroep Kindergeneeskunde MST Enschede;Maatschap Kindergeneeskunde Ziekenhuisgroep Twente en daaraan gebonden stichtingen

Intervention

Keyword: children, dietary advice, nutrition, respiratory infections

Outcome measures

Primary outcome

The main study parameters are the number of infections in six months and the number of days a month with symptoms of URTI, which is calculated as the mean of the number of days with symptoms a month of paediatrician diagnosed URTI in the previous three months.

Secondary outcome

Secondary goals are to assess whether treatment with the dietary advice and standard supportive care compared to standard supportive care alone will influence immunoglobulin levels, decrease number of days absence of child from day-care, decrease number of days absence of parents from work, decrease the number of prescribed antibiotics and a decrease in total cholesterol:HDL-ratio.

Study description

Background summary

Rationale: 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 URTI. This can lead to an increased burden in parental concern and productivity, as well as maintaining a certain degree unnecessary prescription

of antibiotics. Recent studies suggest a beneficial effect of dietary advice consisting of green vegetables, beef and whole dairy products on the number of days with symptoms. There are no randomised controlled trials that investigated the effects of this treatment.

Study objective

A treatment method of a dietary advice of green vegetables, beef and whole dairy products during twelve months including standard supportive care can decrease the number and duration of upper respiratory tract infections compared to standard supportive care alone in children aged 1-4 years with recurrent upper respiratory tract infections.

Study design

A multicentre randomised controlled trial will be performed, with an intervention group receiving standard supportive care plus the dietary advice and a control group receiving standard supportive care alone.

Intervention

A dietary advice: 5 times a week green vegetables, 3 times a week beef, 300 mL whole milk a day, whole butter on bread. Portion sizes are age appropriate.

Study burden and risks

The only risk above the risk of every day life is one extra venapunction, the other procedures are considered to be risk-free. The dietary advice is not complex and hardly a burden. The peak incidence of URTI in children is in the first 5 years of life, justifying the choice of treatment group aged 1-4 years.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Age 1-4 years.
Recurrent URTI (>3 in 3 months).
Understanding of Dutch language (parents).

Exclusion criteria

Immunological deficiencies.
Cow's milk allergy.
Known or suspected disorder of intestinal absorption.
Prophylactic use of antibiotics.
Disorders requiring a special diet.
Any relevant congenital abnormality, chormosomal disorder or severe disease.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-03-2015
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	16-02-2015
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL50373.044.14
Other	nummer volgt/Nederlands Trial Register