

Prevention of asthma and respiratory symptoms in young children with a nutritional intervention

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Objective: Foods consisting of locally grown seasonal vegetables, beef, whole milk and dairy butter with a balanced composition of omega 3 and 6 fatty acids and a wide range of essential micronutrients positively influences the developing immune...

Ethical review	Approved WMO
Status	Completed
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

Summary

ID

NL-OMON52918

Source

ToetsingOnline

Brief title

Asthma Nutritional intervention

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym

Asthma, bronchusobstruction

Research involving

Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente

Source(s) of monetary or material Support: Stichting astma bestrijding

Intervention

Keyword: asthma, children, dietary advice, milk

Outcome measures

Primary outcome

Main study parameters/endpoints: a decrease in TRACK scores and LRSQ scores of the dietary intervention group compared to the control group.

Secondary outcome

Secondary outcome measures are medication use, microbiome, immune analysis (cytokine profile, selective antibody production), IgA in saliva, adherence to the diet as well as growth parameters such as height, weight and Body Mass Index (BMI).

Study description

Background summary

Rationale: Genetic factors for asthma are potentially present, but depending on internal and environmental factors whether the disease actually manifests itself. Nutrition in children affects the growth and development of the body. Nutrition can play a role in immunological stabilisation or derailment of the immune system. The immune system is thought to be a regulator of asthma and airways inflammation by producing too many immune factors in response to a stimuli that should not cause such a reaction. Can nutrition in the young child stabilize the immune system and by that be one of the factors that can influence the onset of asthma?

Study objective

Objective: Foods consisting of locally grown seasonal vegetables, beef, whole milk and dairy butter with a balanced composition of omega 3 and 6 fatty acids and a wide range of essential micronutrients positively influences the developing immune system of a child. Therefore, can it have a protective effect on the development of asthmatic complaints in young children (1-4 years) expressed in reduced TRACK and LRSQ scores?

Our secondary objective is to see changes in immunological parameters and the microbiome between the intervention group and the control group.

Study design

Study design: a randomized controlled multicentre trial

Intervention

Intervention: a dietary advice of four unprocessed food products (NOVA 1 or 2 classification foods);
300 ml full fat (3.4%) milk or yoghurt per day, 5 grams of butter per slice of bread, about 100 grams of seasonal vegetables and 50-60 grams of beef. The dietary intervention will be followed for 6 months.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: We intend to conduct an intervention study in young children (1-4 years) with asthmatic symptoms and a high risk of developing asthma. The study will focus on the preventive effect of a nutritional intervention. Currently, there is no preventive strategy to prevent asthma in high-risk children. This study can contribute to the development of a strategy with the intention to prevent a chronic disease or reducing respiratory symptoms.

previous studies have shown that the dietary advice can be well followed by parents (>75%).

There are no additional risks associated with participating in this study

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Inclusion criteria are;

- Children between 1 and 4 years old
- Paediatric Asthma Score is 7 or above 7, with these scores there is a high chance of developing asthma (chance>25%).

Exclusion criteria

- not understanding the Dutch language by the parents
- a cow's milk protein allergy (or any other allergy to one of the components of the food intervention) at the time of the intervention. If patients never consumed cow*s milk proteins before, the risk of an allergy is unclear. In that case they cannot be included. If they have proven to tolerate cow*s milk protein in whatever form, they can be included.

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL	
Recruitment status:	Completed
Start date (anticipated):	15-09-2020
Enrollment:	114
Type:	Actual

Ethics review

Approved WMO	
Date:	07-08-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO	
Date:	20-10-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO	
Date:	02-04-2025
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	NL73584.100.20