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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21537

Source
NTR

Brief title
TBA

Health condition

asthma

Sponsors and support

Primary sponsor: Hospital Group Twente, NL
Source(s) of monetary or material Support: Stichting Astma bestrijding

Intervention

Outcome measures

Primary outcome

The primary objective will be the difference between the intervention and control group in TRACK score and more extensive respiratory symptoms questionnaire (LRSQ) scores.

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 BMI.

Study description

Background summary

SUMMARY

Rationale: Genetic factors for asthma exist but are 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?
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: a randomized controlled multicentre trial
Study population: Children between 1 - 4 years old with a Paediatric Asthma Risk Score ≥ 7.
Intervention: a dietary advice of four unprocessed food products (NOVA 1or 2 classification foods, see appendix 2);
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 12 months.
Main study parameters/endpoints: a decrease in TRACK scores and LRSQ scores of the dietary intervention group compared to the control group.
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).
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.

Study objective

Foods consisting of whole dairy, butter, beef and locally grown seasonal vegetables with a balanced composition of omega 3 and 6 fatty acids and a wide range of essential micronutrients and anti-inflammatory capacities have a protective effect on the development of asthma complaints in young children (1-4 years).

Study design

t=0 (inclusion), t=3 and 6 months (first evaluation), t=12 months (end-evaluation)

Intervention

The dietary intervention is advised for 12 months. It consists of 4 unprocessed food components (NOVA 1/2 classification);
-daily dairy butter on each slice of bread (5 grams per slice)
-daily 300 ml full fat milk/ yoghurt,
- 3x a week 50 grams of beef at supper
- 5x a week 1-2 serving spoons of seasonal vegetables at supper
All components in age-appropriate portions according to the Dutch Health Council

Contacts

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Eligibility criteria

Inclusion criteria

- Children between 1 and 4 years old

- Paediatric Asthma Score ≥7

Exclusion criteria

-not understanding the Dutch language by the parents
-Allergy for one or more of the components of the dietary intervention

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-08-2020
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	03-07-2020
Application type:	First submission

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
NTR-new	NL8752
Other	MEC U : Registratienummer R20.044/ NL-nummer NL73584.100.20

Study results