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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21537

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

asthma

Ondersteuning

Primaire sponsor: Hospital Group Twente, NL
Overige ondersteuning: Stichting Astma bestrijding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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088-7085818

Wetenschappelijk

Ziekenhuis Groep Twente
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Children between 1 and 4 years old
- Paediatric Asthma Score ≥7

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-08-2020
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	03-07-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8752
Ander register	MEC U : Registratienummer R20.044/ NL-nummer NL73584.100.20

Resultaten