Nutrition and asthma: subgroups and outcomes

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1) To assess differences in nutritional intake and status, by asthma subgroups (e.g. early vs late onset; allergic vs non-allergic; eosinophilic vs non-eosinophilic; obese vs non-obese; moderate vs severe). 2) To explore associations of nutritional...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27753

Bron
Nationaal Trial Register

Verkorte titel
ORANGE

Aandoening

(Severe) asthma

Ondersteuning

Primaire sponsor: Medical Centre Leeuwarden
Overige ondersteuning: Medical Centre Leeuwarden
University of Groningen/Campus Fryslân

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Nutritional intake and status:

- Intake: dietary intake of macro- and micronutrients and food groups, and the Dietary Inflammatory Index;
- Status: body composition (fat mass and fat-free mass), anthropometry (BMI, waist- and hip circumference), muscle mass (urinary creatinine excretion), muscle strength (handgrip strength), functional exercise capacity (6-minute walking test), and nutrient status (plasma vitamins, minerals, lipids).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Asthma is an increasing problem in the western industrialized nations, which has been suggested to be related to environmental exposures and lifestyle changes, particularly diet. Asthma is a heterogeneous condition with many clinical and inflammatory subgroups. In particular for late-onset eosinophilic asthma, exogenous trigger factors, other than allergens, have been suggested to induce the highly inflammatory status, including dietary factors. The Western diet has been thought to promote a pro-inflammatory environment, due to factors such as lack of antioxidants and abundance of saturated fatty acids. Dietary antioxidants (e.g. vitamin A, C, E, and selenium) might protect lung tissue against oxidative damage, in response to exposures such as air pollution and airway inflammatory cell responses. On the other hand, excess fat intake may induce activation of the innate immune system and inflammatory pathways. By contrast, the Mediterranean diet, which is deemed more anti-inflammatory, has been associated with fewer asthma symptoms and improved asthma control.
Furthermore, poor nutritional status, weight loss and muscle wasting have been associated with lower quality of life, lower physical exercise performance and higher risk of exacerbation in patients with chronic obstructive pulmonary disease, a closely linked inflammatory airway disease. The existence of both airway and systemic inflammation in severe asthma patients may also lead to loss of muscle mass and subsequently declined nutritional status. However, no studies have examined the role of nutritional status on clinical, functional and inflammatory asthma outcomes yet.
Although the role of diet in asthma has gained interest in literature, the evidence is inconclusive. It remains unclear whether nutritional factors are related to the different types of inflammation in asthma, and the various asthma subgroups. The capacity of nutritional intake and status to alter disease outcome (e.g. on asthma control, lung function, quality of life) remains underexplored.

Primary objective:
1. To assess differences in nutritional intake and status, by asthma subgroups (e.g. early vs late onset; allergic vs non-allergic; eosinophilic vs non-eosinophilic; obese vs non-obese; moderate vs severe)

Secondary objective:

2. To explore associations of nutritional intake and status, with clinical, functional and inflammatory characteristics of asthma
a. To assess differences in these associations between asthma subgroups

Study design: This study is a cross-sectional study and will be performed in two clinical settings at the MCL Pulmonary Department: 1) the 1-day visiting programme of the Severe Asthma Centre (tertiary referral for difficult-to-control/severe asthma) and 2) the general Asthma Outpatient Clinic (moderate to severe asthma).
The study includes two times of extra assessments added to regular visits to the pulmonary department. The first visit will include anthropometric measurements, a bio-electrical impedance analysis and a handgrip strength test. Patients of Asthma Outpatient Clinic will also perform the 6-minute walking test. This walking test is already part of regular care for patients of the Severe Asthma Centre. Furthermore, in addition to regular blood testing 40 ml extra blood will be drawn, of which 10 ml will be stored for potential future research.
Prior to the second visit, all patients will complete the dietary assessment (two questionnaires and a 3-day food record), a physical activity questionnaire and collect a 24-hour urine sample at home. The dietary assessment will be discussed during the second visit.

Study population: Patients (≥18 yr) with moderate to severe asthma will be consecutively recruited from the Pulmonary Department of the Medical Centre Leeuwarden. Patients are eligible for inclusion when they have been treated according to the Global Initiative for Asthma (GINA) steps 3-5, and are proficient in the Dutch language. Exclusion criteria are: concurrent respiratory disease; pulmonary infection or asthma exacerbation in the past 4 weeks; and pregnancy.

Main study endpoint: Nutritional intake and status
- Intake: dietary intake of macro- and micronutrients and food groups, and the Dietary Inflammatory Index;
- Status: body composition (fat mass and fat-free mass), anthropometry (BMI, waist- and hip circumference), muscle mass (urinary creatinine excretion), muscle strength (handgrip strength), functional exercise capacity (6-minute walking test), and nutrient status (plasma vitamins, minerals, lipids).

Secondary study endpoint: Clinical, functional and inflammatory characteristics of asthma
- Clinical: asthma control (ACQ), quality of life (AQLQ), hospital admissions, exacerbation frequency, and use of oral corticosteroids (health care utilization)
- Functional: pulmonary function (spirometry), and medication use;
- Inflammatory: airway inflammation (FeNO, sputum mRNA, leukocytes and cell differential), systemic inflammation (plasma albumin, IL-6, TNF-α, CRP), innate immune activity (plasma leukocytes and cell differential), and atopic status (IgE and RAST)

The results of this study may be important for asthmatic patients, as it may identify differences in nutritional intake and status in subgroups of asthma patients. Furthermore, this study may help to understand the relation between nutritional intake and status and clinical, functional and inflammatory characteristics of asthma. However, there are no personal direct benefits for the participants. We think the potentially obtainable knowledge outweigh the risks and discomfort of this study.

Doel van het onderzoek

1) To assess differences in nutritional intake and status, by asthma subgroups (e.g. early vs late onset; allergic vs non-allergic; eosinophilic vs non-eosinophilic; obese vs non-obese; moderate vs severe).
2) To explore associations of nutritional intake and status, with clinical, functional and inflammatory characteristics of asthma; and to assess differences in these associations between asthma subgroups.

Onderzoeksopzet

The study includes two times of extra assessments added to regular visits to the pulmonary department. The first visit will include anthropometric measurements, a bio-electrical impedance analysis and a handgrip strength test. Patients of Asthma Outpatient Clinic will also perform the 6-minute walking test. This walking test is already part of regular care for patients of the Severe Asthma Centre. Furthermore, in addition to regular blood testing 40 ml extra blood will be drawn, of which 10 ml will be stored for potential future research.
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Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Asthma diagnosis according to GINA guidelines
- Step 3-5 treatment (GINA guidelines)
- Aged ≥18 year
- Proficient in speaking and understanding Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Pregnancy
- Concurrent respiratory disease (e.g. pneumonia, bronchitis, COPD)
- Pulmonary infection or asthma exacerbation in the past 4 weeks

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2019
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48410
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7614
CCMO	NL69404.099.19
OMON	NL-OMON48410

Resultaten