Observational study into the Relationship between Asthma and Nutrition in asthma sub-Groups including clinical, functional and inflammatory Endpoints

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Primary objective1. 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 objective2. To...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON48410

Source
ToetsingOnline

Brief title
ORANGE
Nutrition and asthma: subgroups and outcomes

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma, pulmonary disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Ministerie van OC&W,Medisch Centrum Leeuwarden

Intervention

Keyword: Asthma, Body composition, Nutrition

Outcome measures

Primary outcome

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 outcome

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)

Study description

Background summary

Asthma is an increasing problem in the western industrialized countries, 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. Likewise, 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.

Study objective

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).

Study burden and risks

The burden associated with this study includes two times of extra assessments added to regular visits to the pulmonary department. For a subset of patients only one assessment can be combined with regular care and therefore an extra visit is requested of them. Each assessment will last approximately 45-60 minutes. 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 as part of research. 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.
The risks and disadvantages of this study are small. Participants may experience discomfort from collecting a 24-hour urine sample. Blood withdrawal may also cause discomfort and pain, but this is combined with blood collection in regular care and will therefore not cause extra discomfort.
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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-06-2019
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	29-04-2019
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	30-08-2021
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 27753

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL69404.099.19
OMON	NL-OMON27753