An assessment of nutritional deficiencies in patients with primary antibody deficiency and bronchiectasis.

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Primary Objective: To assess dietary intake of macro- and micronutrients, body composition and serum levels of nutrients in patients with primary antibody deficiency and bronchiectasis. Secondary Objective(s): - To evaluate the correlation between...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON46112

Source
ToetsingOnline

Brief title
BE-PAD nutrition study (pilot)

Condition

- Other condition
- Immunodeficiency syndromes

Synonym
defects of immune system, immune deficiency

Health condition

bronchiectasieen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: bronchiectasis, nutrition, primary antibody deficiency, recurrent infections

Outcome measures

Primary outcome

7.1.1 Main study parameter/endpoint

- Dietary intake of micro- and micronutrients

- Body composition as estimated with bioelectrical impedance analysis

- Serum levels of micro- and macro nutrients

Secondary outcome

7.1.2 Secondary study parameters/endpoints

- demographic information,

- height, weight,

- type of PAD,

- extent of bronchiectasis as measured by BRICS score,

- lung function (FEV1/ FVC)

- exacerbation frequency in year prior to study inclusion

- markers of systemic inflammation (CRP/ WBC count)

- sputum microbiology

- Bronchiectasis severity scores (BSI and FACED scores)

- QoL and symptoms as measured by LRTI-VAS, CVID-QoL and QOL-B

Study description

Background summary

Primary antibody deficiencies (PAD) are the most frequently encountered immune deficiency disorders in men. Affected individuals suffer from an increased susceptibility for infections, caused by either a shortage or a loss of function of antibodies (immunoglobulins). A wide range of primary antibody deficiency syndromes exists, the most prevalent of which are selective IgA deficiency (1:600) and common variable immune deficiency (1:25.000). Substantial morbidity and mortality arises from the different complications of PAD, which may vary from granulomatous or lymphoproliferative disorder in CVID to severe opportunistic infections or auto-immunity in Good*s syndrome (thymoma-associated hypogammaglobulinemia). However, the most frequently encountered complications of PAD are various forms of respiratory disease, most often bronchiectasis [1]. Bronchiectasis, which has been found to be present in roughly a quarter of patients with PAD, is defined by widening of the large and medium size bronchi as a result of increased burden of infection and concomitant inflammation. Key symptoms in bronchiectasis are recurrent airway infections and chronic symptoms such as dyspnoea and a debilitating productive cough [2].
Immune globulin administration has been standard of care in most PAD for over 25 years now and has induced a significant improvement of morbidity and mortality due to a reduction in the incidence of acute infections in patients with PAD [3].
Concomitant bronchiectasis, when symptomatic, is usually treated with measures to improve sputum evacuation such as dedicated physiotherapy and hypertonic saline inhalations. In addition, patients who experience frequent exacerbations despite these measures may be treated with maintenance antibiotics, most frequently macrolides [4].
In many cases, these treatment modalities reduce the occurrence of new infections and alleviate chronic symptoms in patients with a PAD and bronchiectasis. However, a large subset of patients keeps having frequent infectious exacerbations and/or chronic pulmonary symptoms, despite adequate treatment. In addition, some of the above mentioned measures have important downsides which makes them unattractive for application in some patient groups. For instance, macrolides were noted to cause side effects in almost half of patients treated with azithromycin in a randomized clinical trial [4]. Apart from this, widespread use of macrolide antibiotics is at itself not desirable, because of its tendency to induce macrolide resistance on a population level. This problem may become more urgent in the near future, because the recent publication of randomized trials showing a favourable effect of long term macrolide treatment, not only in bronchiectasis, but also in asthma and COPD, prompted many clinicians to prescribe long term antibiotics in patients with frequent exacerbations.

The above provides arguments for a search for new treatment modalities and for measures which further strengthen the immune system in order to prevent infections and other symptoms in patients with PAD and bronchiectasis.

In a decade where nutrition and food gets more and more attention, exploring the role of diet and deficiencies appears a logical step forward. Nutritional interventions may have the ability to reduce inflammation and as such to reduce the frequency of infectious exacerbations. In addition, most dietary measures are cheap and feasible in most clinical and outpatient settings.

For the immune system to function efficiently, adequate dietary intake is required. This interaction between dietary habits and immunity has been well recognized for decades [5;6], . Nutritional deficiencies are known to cause increased susceptibility to infections, by interacting with innate and cellular immunity [7;8].
In turn, (chronic) infections may be the cause of nutritional deficiencies by reducing dietary intake in general or increased turnover of nutrients [9].
PAD patients, suffering from recurrent infections, will therefore be specifically at risk both to develop nutritional deficiencies and to suffer from the increased susceptibility for infections caused by deficiencies.

Several nutrients have been investigated for their effect on the immune system, the most familiar of which is vitamin C, which was found to reduce systemic inflammation in healthy volunteers and to play a role in facilitating cure in common cold and upper airway infections [10;11]. But also other nutrients, such as vitamin A, B6, B12, folic acid and selenium, iron and zinc were found to improve immune function through various pathways [6].
Interventional studies in this area are scarce, only reflecting the need for more research in this specific field. However, the available evidence so far shows a consistent trend to improved immune function following suppletion of vitamins, minerals and/or trace elements in health volunteers and specific patient groups [12].

Study objective

Primary Objective:
To assess dietary intake of macro- and micronutrients, body composition and serum levels of nutrients in patients with primary antibody deficiency and bronchiectasis.

Secondary Objective(s):
- To evaluate the correlation between disease severity, dietary intake, body composition and serum levels of micro- and macronutrients.

Study design

This is an observational pilot study in 25 patients with a PAD and bronchiectasis, visiting both the outpatient department for primary immune disorders of the department of immunology and the pulmonology outpatient clinic.

For each patient, one study visit will be scheduled, at which they will be seen by a dietician for evaluation of dietary intake and calculations of recommend intake for macro- and micronutrients. In addition, body composition will be estimated using bioelectrical impedance analysis (BIA). At the same occasion, blood samples will be taken in order to test for levels of micronutrients and each patient will be asked to fill out 3 questionnaires on QoL and symptoms (LRTI-VAS, CVID-QoL and QOL-B) (see attachment).

Baseline characteristics of all participants will be collected by chart review

Study burden and risks

limited to the risks involved in venous blood sampling and regarded as negligible.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3000 CA
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3000 CA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Diagnosis of primary antibody deficiency
- Bronchiectasis diagnosed by chest CT scanning
- Informed consent

Exclusion criteria

- Inability to give informed consent
- Active infection/ exacerbation requiring antibiotic treatment in the 2 weeks prior to study inclusion

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-10-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL65924.078.18