The influence of mannose-binding lectin (MBL) on the course of disease in patients with cystic fibrosis (CF).

Published: 13-10-2006
Last updated: 20-05-2024

1. To study the possible association between MBL-deficiency and the occurence and severity of infections in MBL-deficient CF patients.2. To study the possible association between MBL-deficiency and the severity of cystic fibrosis.3. To study the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Skin and subcutaneous tissue disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON29945

Source
ToetsingOnline

Brief title
MBL in CF patients

Condition

- Skin and subcutaneous tissue disorders NEC
- Immunodeficiency syndromes
- Hepatobiliary neoplasms malignant and unspecified

Synonym
Mannose-binding lectin deficiency / deficit of a protein of the immune system

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Landsteiner Stichting voor Bloedtransfusie Research (LSBR)

Intervention

Keyword: Cystic fibrosis, Infections, Innate immunity, Mannose-binding lectin

Outcome measures

Primary outcome

1. Frequency and severity of infection

2. Lung transplantation

Secondary outcome

Secondary endpoints

1. Severity CF

2. Phagocytosis of micro-organisms, specific for CF

Study description

Background summary

About one third of the DUtch population has deficient plasma levels of the protein mannose-binding lectin (MBL) and is thus MBL-deficient. MBL-deficiency is associated with an increased susceptibility to infections, especially in children and the immunocompromized. In patients with cystic fibrosis (CF) an association has been found between MBL-deficiency and reduced lung function. We hypothesize that MBL-deficient CF patients also have an increased susceptibility to infection, possibly due to an increased risk of infection with specific microorganisms. If there is an association, determination of MBL phenotype or genotype might lead to the identification of at risk patients in the future.

Study objective

1. To study the possible association between MBL-deficiency and the occurence and severity of infections in MBL-deficient CF patients.
2. To study the possible association between MBL-deficiency and the severity of cystic fibrosis.

3. To study the phagocytosis of different CF-specific microorganisms in MBL-deficient and MBL-sufficient CF patients.

Study design

Prospective cohort study, multicenter

Study burden and risks

We want to take a blood sample of 5 ml once (10 ml in adults). Since blood is drawn for routine care at least once a year from most CF patients, the burden and risks of our research will be minimal.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)

Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

patients with cystic fibrosis

Exclusion criteria

inability/unwillingness to donate blood

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2006
Enrollment:	170
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL12937.018.06