Prognostic factors in chronic rejection after human lungtransplantation

Published: 05-09-2006
Last updated: 20-05-2024

The primary objective is acquiring insights in the development of BOS in patients after human lung transplantation in an early phase of the disease which can be used to improve immunotherapeutic handling in order to prevent or delay the onset of BOS...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON35319

Source
ToetsingOnline

Brief title
BOS

Condition

- Other condition
- Viral infectious disorders
- Bronchial disorders (excl neoplasms)

Synonym
bronchiolitis obliterans syndrome, rejection

Health condition

genetische pathogenese

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Roche Organ Transplantation Research Foundation

Intervention

Keyword: Bronchiolitis Obliterans Syndrome, chronic rejection, lung transplantation

Outcome measures

Primary outcome

Prediction of BOS in patients after human lung transplantation in an early

phase of the disease.

Secondary outcome

Reactivity of T cells against target antigens as detected by the SEREX techique.

Relation of respiratory viruses and the development BOS.

Relation of respiratory viruses and the development of BOS.

Relation of genetic profile and the development of BOS.

Relation of proteins in condensated breath in patients after human lung

transplantation and the development of BOS.

Study description

Background summary

Survival after lung transplantation is limited by the occurrence of obliterative bronchiolitis, which is characterised by the presence of bronchiolar inflammation and fibrosis in conjunction with progressive airflow obstruction. The pathogenesis is not well known but is associated with repeated injury to the graft by ischemia-reperfusion injury, rejection, infection and inflammatory reactions leading to damage of the airway epithelium followed by an exaggerated healing response. The development of Bronchiolitis Obliterans is usually characterized by a poor response to augmented immune suppression, but

may be effective in an early phase of the disease. In this study we will acquire insights in the multiple immunologic, biological, genetic and inflammatory effects on the transplanted lung in relation to the development of BOS.

Study objective

The primary objective is acquiring insights in the development of BOS in patients after human lung transplantation in an early phase of the disease which can be used to improve immunotherapeutic handling in order to prevent or delay the onset of BOS.

Study design

observational cohort study

Study burden and risks

Because of the additional blood samples, a total of 24 x 40 ml in 4 years, there is a possibility of developing anemia. When this occurs and has therapeutic consequences the additional blood samples will temporarily be stopped.

Contacts

Public
Academisch Medisch Centrum

Heidelberglaan 100
Utrecht
NL
Scientific
Academisch Medisch Centrum

Heidelberglaan 100
Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients who undergo a lung transplantation

Exclusion criteria

none

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):	02-01-2007
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO Date:	05-09-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-11-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL12752.041.06