Use of novel lung injury markers to predict graft dysfunction after lung transplantation

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational invasive

Summary

ID

NL-OMON34782

Source
ToetsingOnline

Brief title
Lung injury markers

Condition

- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
chronic bronchitis, Chronic obstructive pulmonary disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Biomarkers, Lung transplantation

Outcome measures

Primary outcome

The primary endpoint is primary graft dysfunction in the first 72 hours as defined by a classification system from the international society for heart and lung transplantation.

Secondary outcome

1. Assessment of biomarkers, measured during and post operation (in the recipient), that correlates with the graft function after lung transplantation.

2. Assessment of biomarkers, measured during and post operation (in the recipient), that quantifies primary graft dysfunction.

Study description

Background summary

The main reason for early morbidity and mortality after lung transplantation is primary graft dysfunction (PGD). There are several factors that may influence the occurrence of PGD (such as; brain death, mechanical ventilation, hypotension, trauma or pneumonia) but there is no variable as yet, measured in a donor blood sample, that can predict the occurrence of PGD. Although donor variables strongly influence the occurrence of PGD, also recipient variables contribute to the occurrence of PGD.

Study objective

The primary objective is to identify biomarkers measured in donor and recipient blood before lung transplantation which can predict lung graft function after lung transplantation. When the risk of PGD can be predicted, more adequate therapy can be applied, preventing severe morbidity and mortality.

Study design

Prospective cohort study

Study burden and risks

The burden of participation is that during the first 72 hours after transplantation a total of 75ml of blood will be taken out off the venous or arterial line. These lines are part of standard care. No further physical or mental burden is present. No increased risk is inflicted. In case of removal of venous and arterial lines, blood will be sampled by vena punction during standard blood sampling for clinical use. The study relates to recipients with a lungtransplant, who due to objective research factors only influence PGD in lung transplantation.

Contacts

Public
Universitair Medisch Centrum Groningen

A. Deusinglaan 1
9713 AV
NL
Scientific
Universitair Medisch Centrum Groningen

A. Deusinglaan 1
9713 AV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Age >< = 18 years
First lung transplantation
Informed consent

Exclusion criteria

Hyperacute rejection
Venous anastomotic obstruction
Cardiogenic pulmonary edema
Pneumonia (both viral and bacterial pneumonias will be considered)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2011
Enrollment:	38
Type:	Actual

Ethics review

Approved WMO

Date:	27-05-2010
Application type:	First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL30984.042.10