Bronchiolitis obliterans syndrome and other allo-reactive lung syndromes after allogeinic hematopoietic stem cell transplantation
Is early prediction of bronchiolitis obliterans possible by using biomarkers possible?

Published: 19-02-2013
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In this study we would like to find new biomarkers in BOS after haematopoietic stem cell transplantation (HSCT), that may lead to earlier identification of BOS than a lung function decline.

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

Summary

ID

NL-OMON44102

Source
ToetsingOnline

Brief title
Bronchiolitis obliterans after hematopoietic stem cell transplantation

Condition

- Other condition
- Respiratory disorders NEC

Synonym

chronic lung rejection bronchiolitis obliterans, lung rejection after hematopoietic stemcell transplantation

Health condition

afstoting na beenmergtransplantatie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bronchiolitis obliterans, stemcell transplantation

Outcome measures

Primary outcome

Identifying biomarkers in the peripheral blood that predict BOS by a sgnificant

elevation before a lungfunction decline occurs (i.e. a drop in FEV1 of 20%)

after allogeneic hemtopoietic stem cell transplantation.

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Secondary outcome

To determine the incidence and outcome of allo-reactive lung syndromes (i.e.

BOS and other ARLS) in patients that underwent allogeneic haematopoietic stem

cell transplantation.

Study description

Background summary

Graft versus host disease after allogeneic hemtopoietic stem cell transplantation (HSCT) may cause allo-reactive lung syndromes (ARLS) and

especially bronchiolitis obliterans syndrome (BOS). In its clinical and histological appearance it closely resembles the bronchiolitis obliterans syndrome that occurs in patients after lung transplantation due to chronic rejection. In previous studies we have described specific biomarkers for the bronchiolitis obliterans syndrome after lung transplantation.

Study objective

In this study we would like to find new biomarkers in BOS after haematopoietic stem cell transplantation (HSCT), that may lead to earlier identification of BOS than a lung function decline.

Study design

All patients that have been selected for allogeneic HSCT at the UMC Utrecht will be included and followed for 3 years. Spirometry, and blood samples will be performed before and after stem cell transplantation. Blood samples will be drawn to investigate biomarkers that may be predict BOS earlier than a drop of 20 % in forced expiratory volume in one second measuresd by spirometry which is the current standard to diagnose BOS .
We will use biomarkers we have used in BOS after lung transplantation and by using Luminex assays we will search for new biomarkers in the peripheral blood

Study burden and risks

Selection criteria of patients for allogeneic hemtopoietic stem cell transplantation (HSCT) are not dependent on our study. This study does not intervene with the indication for HSCT or treatment of HSCT patients. There are no additional risks for these patients. Additional blood samples are taken with known very low acceptable risks like haematoma or local pain during blood sampling. When the hemoglobin value decreases below 5 mmol/L no additional blood will be drawn. Lung function measurements have no additonal risk but may be tiresome.

Contacts

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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 whom are selected for hematopoietic stem cell transplantation

Exclusion criteria

no informed consent
all patients after hematopoietic stem cell transplantation will be included except patients that do not want to participate in this study.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-12-2013
Enrollment:	360
Type:	Actual

Ethics review

Approved WMO Date:	19-02-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-01-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-09-2016
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	NL38645.041.11