Imaging lung lymphocytic infiltration with radiolabelled Interleukin-2 in the follow-up of patients with lung transplantation; a marker of acute rejection

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To evaluate the ability of the IL-2 scan tot detect the presence of acute rejection in the transplanted lungs and the correlate the uptake of IL-2 with the histopathological findings after transbronchial biopsy.

Ethical review	Approved WMO
Status	Pending
Health condition type	Thoracic disorders (excl lung and pleura)
Study type	Observational invasive

Summary

ID

NL-OMON33003

Source
ToetsingOnline

Brief title
99mTc-IL2 for imaging lymphocytic infiltration after lung transplantation

Condition

- Thoracic disorders (excl lung and pleura)

Synonym
acute rejection, lung transplantation

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: interleukin-2, lung transplantation, nuclear medicine, rejection

Outcome measures

Primary outcome

Evalution of IL-2 scan to detect acute rejection. Comparison between IL-2

uptake and histopathological findings.

Secondary outcome

Nvt

Study description

Background summary

One of the major complications after a lung transplantation is the acute allograft rejection. The use of several immunosuppressive agents contributes to improve short-term transplant outcome. Nevertheless, about 1 in 3 patients suffer from acute rejection. Till now, transbronchial biopsy and histopathological examination is the method to discover acute rejection. Histopathological lesions show a T-cell dependent lymphocytic infiltration, which is driven by interleukin-2 (IL-2), among others. The use of radiolabelled IL-2 (to 99mTc) should therefore allow the in vivo detection of ongoing graft rejection by imaging activated and infiltratinfg lymphocytes in the grafted lungs.

Study objective

To evaluate the ability of the IL-2 scan tot detect the presence of acute rejection in the transplanted lungs and the correlate the uptake of IL-2 with the histopathological findings after transbronchial biopsy.

Study design

Mono-center, observational study

Study burden and risks

The only extra burden is the IL-2 scan. One hour after injection the patients will be scanned during a 45 minute period. The total duration will approximately be 2 hours.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All patient with lung transplantation

Exclusion criteria

Children, pregnant and lactating women

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2009
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

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	NL28951.042.09