3D mini lung structures from skin cells

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

Summary

ID

NL-OMON54612

Source
ToetsingOnline

Brief title
3D mini lungs from skin cells

Condition

- Other condition
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
interstitial lung diseases (ILD), lung diseases

Health condition

ILD

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: fondsen

Intervention

Keyword: disease mechanisms, interstitial lung diseases (ILD), novel therapies, skin biopsy

Outcome measures

Primary outcome

not applicable

Secondary outcome

not applicable

Study description

Background summary

Currently, the etiopathogenesis of most interstitial lung diseases (ILD) is still unknown and the treatment options are limited. Human in vitro tissue systems that faithfully reproduce in vivo ILD lung tissue could facilitate investigation of disease mechanisms and the development of effective therapies for this devastating disease.

Study objective

Studies have shown that generation of lung cells from human pluripotent stem cells is possible. The present study aims to develop cell cultures, such as 3D mini lung structures from skin cells from subjects with ILD and/or their family members. The generated cell culturs will be used for research by researchers of renowned laboratories and the St Antonius hospital.

Study design

A small skin biopsy from subjects with ILD and/or their family members will be used to develop cell cultures

Study burden and risks

a little scar from the skin biopsy, colouring of the skin (bruise), and a small chance of a little bleeding.

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

ILD and/or their family members

Exclusion criteria

none

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):	18-09-2017
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	23-02-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-05-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-12-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-05-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL58379.100.16