Next-Generation Organ-on-a-Chip model for research and drug evaluation in fibrotic diseases

Published: 05-10-2023
Last updated: 16-11-2024

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

Summary

ID

NL-OMON56191

Source
ToetsingOnline

Brief title
FibOoC

Condition

- Autoimmune disorders
- Epidermal and dermal conditions

Synonym
scleroderma, Systemic sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NWO,BEOnChip,Fluigent,Mercurna,Predica

Diagnostics,Proefdiervrij Nederland

Intervention

Keyword: Fibrosis, organ-on-a-chip, Systemic sclerosis

Outcome measures

Primary outcome

The main study endpoint is evaluation of anti-fibrotic/anti-SSc therapies using patient-specific SSc OoC models.

Secondary outcome

Secondary study parameters include the development of an SSc in vitro model that incorporates key disease features, the investigation of patient-specific disease signatures and assessment of signalling pathways.

Study description

Background summary

Progressive organ fibrosis is a debilitating medical problem that is often caused by chronic inflammation, leading to excessive extracellular matrix (ECM) depositions and ultimately organ failure. Fibrosis is a key hallmark of systemic sclerosis (SSc) andmay affect multiple organs. To date, the mortality of patients with SS is increased and the quality of life is decreased due to the absence of an effective disease-modifying treatment against fibrosis. To add, there is a huge heterogeneity between SSc patients and the disease aetiology is still poorly understood. However, to get a better disease understanding, to identify diagnostic and prognostic biomarkers, perform drug screening and to design clinical trials and precision medicine, a reliable disease model is required. The existing in vitro models lack essential disease features while animal models are unable to completely model a fibrotic disease due to the major interspecies differences. In this study, we will develop an organ-on-a-chip model that incorporates crucial SSc features such as the inclusion of human cell types, extracellular matrix, biomechanical cues and hypoxia. This model will then be used to evaluate anti-fibrotic and anti-SSc therapies.

Study objective

The main objective of this study is to evaluate the effect of anti-fibrotic/anti-SSc therapies using a SSc organ-on-a-chip (OoC) model. The secondary objectives of the study are:
- To engineer an advanced OoC device to model SSc that incorporates key disease features
- To identify specific disease signatures using patient-specific SSc OoC models for patient stratification, to facilitate SSc diagnosis and prognosis and to better understand the aetiology and progression of the disease

Study design

In vitro experimental study; collection of skin biopsies and blood of patients with SSc and blood from healthy volunteers for developing and employing an in vitro research model. The in vitro model will be used to evaluate therapies.

Study burden and risks

For the study, all volunteers will undergo a venapunction which implies only a minor inconvenience for most, but volunteers can stop the blood donation at any time. This is a basic procedure and the risks for all participants are negligible.
All participants with SSc will have skin biopsies taken under local anesthesia, this will be a mild inconvenience as after the procedure the place of the biopsy can hurt for a while and can lead to the formation of a small scar. As this is also a basic procedure the risks for participants are negligible. The results of the study are expected to contribute to a better understanding of the disease in a patient-specific manner, which will lead to more personalized medicine, which in the future will benefit all SSc patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: Patients diagnosed with SSc with the ACR-EULAR 2013 classification criteria, with scleroderma on the forearm. All participants needs to be 18-80 years of age and able and willing to complete the informed consent process.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: Participants with an active inflammatory or infectious co-morbid disease will be excluded.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2024
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO

Date:	05-10-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL82683.091.23