Systemic sclerosis: CT-derived evaluation of interstitial lung disease and pulmonary vasculopathy for assessment of progression of disease.
Research protocol for extended volume HRCT-thorax in patients with systemic sclerosis participating in a 2 *day multidisciplinary team care program of the department of Rheumatology and Pulmonology

Published: 04-02-2015
Last updated: 21-04-2024

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

Summary

ID

NL-OMON44504

Source
ToetsingOnline

Brief title
HRCT thorax in patients with systemic sclerosis and fibrotic lung diseases

Condition

- Autoimmune disorders
- Connective tissue disorders (excl congenital)
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
long fibrosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: health care program, HRCT thorax, systemic sclerosis

Outcome measures

Primary outcome

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Secondary outcome

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Study description

Background summary

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Study objective

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Study design

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Study burden and risks

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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

1. Diagnosis of systemic sclerosis according to ACR/EULAR 2013 criteria or suspected / confirmed fibrotic lung disease
2. Age * 18 years
3. First consultation at Zorgpad Sclerodermie LUMC or the dedicated ILD outpatient clinic and high risk profile* and/or low DLCO/ and/or low FVC which indicates a standard HRCT scan
4. Life expectancy > 6 months

5. Able and willing to undergo annual follow-up for 3 consecutive years
6. Written informed consent

Exclusion criteria

1. Inability to perform pulmonary function testing

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-03-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	04-02-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	09-06-2016
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL49323.058.14