Value based health care in systemic sclerosis: what is the optimal follow-up for patients with systemic sclerosis?

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To evaluate in SSc patients with low risk for disease progression 1) whether assessment in an outpatient clinic setting is an acceptable alternative for evaluation in the Care Pathway. Outcome parameters we will evaluate include 1) health care...

Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Autoimmune disorders
Study type	Interventional research applied for the first time in human subjects

Summary

ID

NL-OMON52574

Source
ToetsingOnline

Brief title
PRASSc

Condition

- Autoimmune disorders
- Connective tissue disorders (excl congenital)

Synonym
systemic sclerosis, scleroderma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Eerste geldstroom (geld van Ministerie van

OC&W aan universiteiten)

Intervention

- Psychosocial intervention

Keyword: Prediction Model, Systemic Sclerosis, Value Based Health Care

Explanation

N.a.

Outcome measures

Primary outcome

1. Primary outcome measures: health care utilization

Secondary outcome

Secondary outcome measure: quality of life of SSc patients and patient*s
 satisfaction and perception of delivery care, and disease progression

Study description

Background summary

Systemic sclerosis (SSc) is a complex multisystem rheumatic autoimmune disease. Currently, evidence based guidelines for frequency and intensity of follow-up of SSc patients are not available. Based on expert consensus annual extensive evaluation is recommended. To provide comprehensive multidisciplinary care integrated with evaluation of organ involvement and as such, reducing health care utilization while improving the quality of care for the patient, the *Leiden Combined Care in SSc (CCISS) pathway* was started in 2009. Data collected on disease progression in the patients that participate in this care pathway show that 50% of the patients have relatively mild disease, without any disease progression over time. Therefore there is a need for tailormade care in SSc patients in accordance to disease activity. To enable this, a prediction model was developed that can identify patients with low risk for disease progression.

Study objective

To evaluate in SSc patients with low risk for disease progression 1) whether

assessment in an outpatient clinic setting is an acceptable alternative for evaluation in the Care Pathway. Outcome parameters we will evaluate include 1) health care utilization, 2) patients* perception of the disease and delivery of care, 3) health-related quality of life and 4) disease progression. Health care utilization as primary outcome is defined as number of contacts with heath care providers during 12 months.

Study design

This study consists of two parts:
1) Applying our prediction model to categorize SSc patients, who have had at least two Care Pathway visits, into three risk categories for disease progression: low, intermediate or high risk group.
2) Among the SSc patients in the low and intermediate risk category for disease progression, a non-inferiority randomized trial will be performed. Patients with a low or intermediate risk score will be randomized for an outpatient clinic visit or a visit in the care pathway. The year after the *study visit*, everyone one will be seen in the care pathway.

Intervention

Based on a machine learning assisted prediction model (unpublished data of our research group) the patients identified as low or intermediate risk profile for disease progression are randomized in two groups: 1) follow-up in the outpatient clinic (intervention) and 2) usual care at the care pathway (control group)

Study burden and risks

This is a non-therapeutic study and the risks for participants are considered low. Only SSc patients who have had two care pathway evaluations and with a predicted low or intermediate risk for disease progression will randomize for the intervention. The cut-offs for defining risk groups were chosen with the aim not to miss disease progression (high negative predictive value); amongst patients classified as low risk no disease progression was observed, while among the patients classified as intermediate risk the chance for progression was < 10%. At all times, patients are allowed to contact the care providers of the Care Pathway in case of questions or symptoms. The number of physical examinations and site visits will not be different between the groups according to the study design. During the follow-up period patients will be asked to complete two additional questionnaires to collect data on health care utilization, and two additional questionnaire on illness perceptions. We try to limit the physiological discomfort associated with participation by given advice and information on the low risks of this study and by assuring patients that they will receive the high quality care in both arms of the study. We will also investigate physiological discomfort with the use of the brief illness

perception questionnaire (BIPQ). After one year, all patients will be evaluated at the SSc care pathway.

Contacts

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Trial sites

Trial sites in the Netherlands

HagaZiekenhuis
Target size: 26

Leids Universitair Medisch Centrum
Target size: 179

Haaglanden Medisch Centrum (HMC)
Target size: 45

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all the following criteria:
1. Participation in the prospective Haga, HMC or LUMC cohort
2. Clinical diagnosis of SSc
3. Age of >=18 years
4. >= two evaluations in the Care Pathway.
5. Low or intermediate risk for disease progression according to the prediction model
6. Written informed consent for this study
a. For participants in the Leiden University Medical Center: additional written informed consent for the Leiden CCISS cohort is required
b. For participants in the Haga Hospital and Haaglanden Medical Center: sufficient data should be available to be able to calculate the risk score

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Patients with SSc who are part of ongoing (randomized) trials
2. Patients who have had an autologous stem cell transplantation in the past five years
3. Patients with SSc who were categorized as high risk for disease progression according to the predictive model.

Study design

Design

Study phase:	N/A
Study type:	Interventional research applied for the first time in human subjects
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	No intervention

Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	14-03-2023
Enrollment:	250
Duration:	24 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.
Registration:	No

IPD sharing statement

Plan to share IPD: Yes

Plan description
Access to the trial database will be granted to all Principal Investigators from participating centers. The dataset with deidentified individual participant data could be made available upon reasonable request, as is the full protocol. Data sharing will have to follow appropriate regulations by Dutch law.

Ethics review

Approved WMO

Date:	13-06-2022
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	02-09-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Notification accepted Date:	12-05-2025
Application type:	Amendment
Review commission:	METC LDD

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
ClinicalTrials.gov	NCT05103553
CCMO	NL74263.058.21
Research portal	NL-006471