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

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

Summary

ID

NL-OMON52574

Source
ToetsingOnline

Brief title
PRASSc

Condition

- Autoimmune disorders
- Connective tissue disorders (excl congenital)

Synonym
scleroderma, systemic sclerosis

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: Prediction Model, Systemic Sclerosis, Value Based Health Care

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

Listed location countries

Netherlands

Eligibility criteria

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

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 as well as the Leiden CCISS cohort
(Comprehensive Care in Systemic Sclerosis)

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 type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 14-03-2023

Enrollment: 250

Type: Actual

Medical products/devices used

Registration: No

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

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