

Attitudes towards risk in systemic sclerosis

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25478

Source

Nationaal Trial Register

Brief title

@RISSC

Health condition

Systemic sclerosis, risk perception, illness perception

Sponsors and support

Primary sponsor: Leiden University Medical Center

Source(s) of monetary or material Support: no funding

Intervention

Outcome measures

Primary outcome

Results about the assessment of illness perceptions, risk perceptions and worry, their interrelations and associations with sociodemographic and clinical characteristics will mainly be descriptive, as the character of this study is exploratory

Secondary outcome

not applicable

Study description

Background summary

Rationale: Being diagnosed with Systemic Sclerosis (SSc) will evoke thoughts about the disease. For physicians, it is almost impossible to tell a patient what his/her disease course will be. The disease is unpredictable, it may show a chronic but mild disease course, but also in a considerable proportion of patients life-threatening complications occur.

Objective: To explore illness perception, risk perceptions and worry in patients with Systemic Sclerosis

Study design: A combined qualitative and quantitative design, using questionnaires, a focus group and letting patients draw their disease

Study population: From the Leiden Combined Care in Systemic Sclerosis cohort six SSc patients with a disease duration of 1 to 2 years, will be included. Patients should have completed at least two visits in the care program.

Methods: The brief illness perception questionnaire (BIPQ) and patient drawings will be used to assess illness perceptions, risk perceptions and worries are examined by questionnaires adapted from Cameron and Diefenbach, 2001 (1). For further in-depth exploration of illness perceptions, risk perceptions and worry, a focus-group will be organised with 6 patients with recently diagnoses systemic sclerosis.

Main study parameters/endpoints: Results about the assessment of illness perceptions, risk perceptions and worry, their interrelations and associations with sociodemographic and clinical characteristics will mainly be descriptive, as the character of this study is exploratory

Study design

one time point

Intervention

The brief illness perception questionnaire (BIPQ) and patient drawings will be used to assess illness perceptions, risk perceptions and worries are examined by questionnaires adapted from Cameron and Diefenbach, 2001 (1). For further in-depth exploration of illness perceptions, risk perceptions and worry, a focus-group will be organised with 6 patients with recently diagnoses systemic sclerosis.

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

Patients included should be diagnosed with SSc > 1 year and < 2 year prior to study entry with an age of 18-55 years. Included patients have to fulfill the ACR/EULAR 2013 criteria (American College of Rheumatology/ European League against Rheumatism), have to have completed a second visit in the care program and have to have started with any kind of medication (prescribed by the rheumatologist) after the first visit. Informed consent will be obtained via written forms .

Exclusion criteria

Patients with serious comorbidities, patients that are medically trained and/or work in a medical setting, and patients with insufficient understanding of the Dutch language will be excluded

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-11-2018
Enrollment: 6
Type: Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL7278
NTR-old	NTR7511
CCMO	NL67104.058.18

Study results