

# MRI and neuropsychological evaluation in systemic sclerosis

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Aim of the project 1) To detect cerebral structural changes in SSc patients. 2) To investigate the influence of chronic inflammation and chronic vasculopathy on the cerebral metabolism and haemodynamic function in SSc patients. 3) To correlate the MRI...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Autoimmune disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON39408

### Source

ToetsingOnline

### Brief title

MRI and neuropsychological evaluation in systemic sclerosis

### Condition

- Autoimmune disorders

### 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:** neuroimaging, neuropsychological evaluation, systemic sclerosis

## Outcome measures

### Primary outcome

The following questionnaires:

Fatigue Index (MVI-20)

the Hospital Anxiety and

Depression Scale (HADS)

the Dissociation Experience Scale (DES), and the Neuropsychiatric Inventory (NPI).

The following functional neuropsychology tests are performed at the department of Neurology:

- a) global functioning (assessed by Mini mental state examination (MMSE),
- b) memory (Wechsler Memory scale),
- c) executive testing (Trails, Stroop, Wais-R substitution, number strike through test,
- d) language: (Word Fluency, naming pictures, writing and calculating)
- e) praxis (drawing a clock, map and cube).

The following neuroimaging parameters:

- 1) Diffusion Weighted Imaging (DWI)
- 2) Single Voxel Proton Magnetic Resonance Spectroscopy (H1-MRS)

## Secondary outcome

Not applicable

## Study description

### Background summary

Systemic sclerosis (SSc) is an autoimmune connective tissue disease. Although initially, involvement of the central nervous system is not considered as a typical feature of the disease, recently there has been increasing evidence that neuropsychiatric manifestations can be clinical manifestations of SSc. In a systematic review it was described that SSc has a significant effect on mental health and fatigue levels, and that SSc affects cognitive performance, especially visual-spatial and problem solving abilities. So far there is limited information on cerebral damage responsible for these symptoms. Previously, researchers from the LUMC departments of Rheumatology, Radiology and Neurology have demonstrated that using advanced neuroimaging techniques the detection and understanding of pathophysiological processes underlying cerebral manifestations of rheumatic diseases (RA, SLE) can be improved. The general aim of this pilot study is to assess whether brain damage can be detected using advanced MRI techniques in SSc patients and to correlate cerebral damage to clinical characteristics (fatigue, cognitive impairment, disease activity and neuropsychological investigation). All subjects will undergo psychiatric and neuropsychological testing as well as an advanced MR imaging protocol. If brain damage can be detected and correlated with neuropsychological symptoms, it would pave the way for a more comprehensive study into the nature of the observed damage, and it would provide essential ammunition for a intervention and therapeutical strategy studies.

### Study objective

Aim of the project

- 1) To detect cerebral structural changes in SSc patients.
- 2) To investigate the influence of chronic inflammation and chronic vasculopathy on the cerebral metabolism

and haemodynamic function in SSc patients.

3) To correlate the MRI changes to clinical characteristics, disease activity parameters and neuropsychological investigation.

## **Study design**

The Psychiatric assessment will be done by a psychiatrist and includes a detailed psychiatric history and mental state examination assessing behaviour, cognition, perception and thinking, as well as mood and affect in a standardized manner. Additionally, the following measures are used for assessment of quality of life, presence of anxiety- and/or depressive disorders, presence of dissociation, and presence of neuropsychiatric symptoms: fatigue index (MVI-20), the Hospital Anxiety and Depression Scale (HADS), the Dissociation Experience Scale (DES), and the Neuropsychiatric Inventory (NPI).

The following functional neuropsychology tests are performed at the department of Neurology: a) global functioning (assessed by Mini mental state examination (MMSE), b) memory (Wechsler Memory scale), c) executive testing (Trails, Stroop, Wais-R substitution, number strike through test, d) language: (Word Fluency, naming pictures, writing and calculating) and e) praxis (drawing a clock, map and cube).

Advanced neuroimaging methods will be performed at the Department of Radiology and comprises: a) a set of conventional MRI sequences (T1-, T2-, FLAIR-, and susceptibility-weighted sequences), b) a quantitative structural sequences (Diffusion Weighted Imaging, DWI), c) a technique for detecting metabolic changes (Single Voxel Proton Magnetic Resonance Spectroscopy, H1-MRS), d) a technique to detect and quantify changes at the level of the cerebral microvasculature (challenged and unchallenged perfusion MRI), and e) a technique to assess presymptomatic functional brain changes (resting-state functional MRI).

## **Study burden and risks**

The patients are doing extra investigations, (half a day): MRI of the brain, neuropsychological tests and completing questionnaires.

## **Contacts**

**Public**

Leids Universitair Medisch Centrum

Albinusdreef 2  
Leiden 2300RC  
NL

**Scientific**

Leids Universitair Medisch Centrum

Albinusdreef 2  
Leiden 2300RC  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

**Age**

Adults (18-64 years)

Elderly (65 years and older)

### **Inclusion criteria**

1. systemic sclerosis according to ACR criteria
2. presence of cognitive dysfunction, fatigue, concentration loss, and/or depression

### **Exclusion criteria**

1. Routine MRI-contraindications (e.g. instable metal implants, pacemaker/ICD, vascular clips, fear).
2. Pregnancy

## **Study design**

## Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Basic science

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	19-10-2012
Enrollment:	200
Type:	Actual

## Ethics review

Approved WMO	
Date:	10-04-2012
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO	
Date:	10-04-2013
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

## 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

CCMO

### ID

NL36942.058.11