MRI and neuropsychological evaluation in systemic sclerosis

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Aim of the project1) To detect cerebral structural changes in SSc patients.2) To investigate the influence of chronic inflammation and chronic vasculopathy on the cerebral metabolismand haemodynamic function in SSc patients.3) To correlate the MRI...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	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 Indez (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 acitivity 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 questionaires.

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. 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	ID
CCMO	NL36942.058.11