

# The Neuropsychiatric Systemic Lupus Erythematosus Clinic, follow up visit

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To evaluate efficacy and accuracy of diagnostic procedure in our NPSLE clinic and to evaluate effects of advised therapy by means of follow-up data

<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-OMON35251

### Source

ToetsingOnline

### Brief title

The NPSLE Clinic, follow up visit

## Condition

- Autoimmune disorders

### Synonym

neuro lupus

### 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:** neuropsychiatric, SLE

## Outcome measures

### Primary outcome

activity of SLE and NPSLE

results of bloodtests, MRI of the brain, and neuropsychological test

results of questionnaires, as taken for psychiatric evaluation (HADS, SF-36, DES)

### Secondary outcome

not applicable

## Study description

### Background summary

NPSLE is a rare diagnosis in which there is a paucity of data. Our center (LUMC) is a tertiary referral clinic and evaluates NPSLE in a standardised manner in a day care clinic since 2007.

### Study objective

To evaluate efficacy and accuracy of diagnostic procedure in our NPSLE clinic and to evaluate effects of advised therapy by means of follow-up data

### Study design

Patients with SLE who visited the NPSLE clinic more than a year ago, and had no objection to be contacted again, are invited to participate in the NPSLE follow up visit. If they wish to participate they will undergo an examination, as comparable to the first visit, all in one day.

### Study burden and risks

There is no extra risk for patients as the examination that they will undergo is considered regular patient care

## Contacts

### Public

Leids Universitair Medisch Centrum

postbus 9600 (bezoek: Albinusdreef 2)  
2300 RC Leiden  
NL

### Scientific

Leids Universitair Medisch Centrum

postbus 9600 (bezoek: Albinusdreef 2)  
2300 RC Leiden  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

SLE patients that have been evaluated in the NPSLE clinic at least one year before this investigation

### Exclusion criteria

patients that have been evaluated in the NPSLE clinic, but who do not fulfill SLE criteria (criteria of American College of Rheumatology)

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 25-01-2012

Enrollment: 65

Type: Actual

## Ethics review

Approved WMO

Date: 25-01-2012

Application type: First submission

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

CCMO

### ID

NL37797.058.11