

The Neuropsychiatric Systemic Lupus Erythematosus Clinic, follow up visit

Published: 25-01-2012

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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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	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