Serum storage of patients with neuropsychiatric systemic lupus erythematosus (SLE)

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To collect and store a serum sample of each patient that is referred to the Leiden University Medical Centre for evaluation of neuropsychiatric symptoms in SLE.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON31369

Source
ToetsingOnline

Brief title
Serum storage of patients with neuropsychiatric SLE

Condition

- Autoimmune disorders

Synonym
Lupus, Systemic Lupus Erythematosus

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, serum, SLE

Outcome measures

Primary outcome

Not applicable

Secondary outcome

Not applicable

Study description

Background summary

Systemic Lupus Erythematosus (SLE) is an autoimmune disease characterized by the presence of autoantibodies. Up to 80 percent of patients with SLE develop neurological or psychiatric symptoms. These symptoms can be the consequence of primary SLE involvement of the brain (primary NPSLE), be the consequence of secondary, SLE-related causes such as side effects of drugs or infections (secondary NPSLE) or have no relation with SLE. Symptoms are diverse and there is no gold standard to diagnose NPSLE, it is still a clinical diagnosis "per exclusionem". Pathogenesis in primary NPSLE is largely unclear, but autoantibodies and a breach in the integrity of the blood-brain-barrier seem to play a role.
The department of Rheumatolgy of the Leiden University Medical Centre is a tertiary referral centre for patients with neuropsychiatric symptoms in SLE. In September 2007, a specialized outpatient clinic for neuropsychiatric SLE will start in the LUMC. In a multidisciplinary setting, patients referred from other hospitals with possible NPSLE, will be evaluated in one day via the Ambulant Department of Rheumatology (Sole Mio), by a neurologist, psychiatrist, vascular internist and rheumatologist. They will undergo neuropsychological testing, MRI scan of the brain (including quantitative MRI) and laboratory tests. After 2 weeks a multidisciplinary meeting is organized and patients visit the outpatient clinic to discuss the results.
Data of all NPSLE patients (clinical, laboratory and radiological) will be registered in a database to be able to describe this population in the future. To enable future research, serum will be stored.

Study objective

To collect and store a serum sample of each patient that is referred to the Leiden University Medical Centre for evaluation of neuropsychiatric symptoms in SLE.

Study design

After informed consent, one bloodsample (10 ml) is drawn by a nurse of the Ambulant Department of Rheumatology (Sole Mio) during routine blood collection neccessary for the evaluation of neuropsychiatric SLE. No additional punction is needed.
Serum samples are coded and stored at -70° in the laboratory of the department of Rheumatology, Leiden University Medical Centre. Serum samples will be stored during 15 years.

Study burden and risks

None

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

Systemic Lupus Erythematosus
neuropsychiatric symptoms

Exclusion criteria

no SLE
no neuropsychiatric symptoms

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission

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	NL18844.058.07