

# Measurement of cognitive functioning and well-being in youngsters with systemic lupus erythematosus (SLE)

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<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-OMON33762

### Source

ToetsingOnline

### Brief title

Cognition and quality of life in juvenile SLE (SMILEY/NPO)

### Condition

- Autoimmune disorders
- Central nervous system vascular disorders
- Cognitive and attention disorders and disturbances

### Synonym

systemic lupus erythematosus

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** cognition, quality of life, systemic lupus erythematosus

## Outcome measures

### Primary outcome

The studieparameters are

- 1) Inventarisation of cognitive functioning of patients with JSLE, using standard tests on intelligence, memory, learning, concentration, executive functions, and rate
- 2) validation of a Dutch translation of a Quality of Life Questionnaire, the so-called SMILEY©, in patients with JSLE

### Secondary outcome

not applicable

## Study description

### Background summary

Systemic lupus erythematosus (SLE) is a rare, chronic multisystem autoimmune disease, with involvement of the central nerve system. It is not known if, and how often SLE disease activity in children and adolescents leads to cognitive functioning disorders. In this cross-sectional study neuropsychological disorders in children with Juvenile SLE (JSLE) will be analyzed.

Due to the multiorgan involvement and the chronicity JSLE disease activity may have impact on several aspects of quality of life. Recently, a short 'Quality of Life' questionnaire was developed, using smiley's©. This questionnaire was validated for English-speaking countries. Translation and validation of the questionnaire into other languages will be of use to compare outcome of treatment strategies in JSLE worldwide.

### Study objective

The goals of this study is twofold:

At first we want to gain insight in neurocognitive functioning of children and adolescents (12-18 year) with JSLE.

Secondly, we want to adapt and validate a Dutch translation of a short "Quality Life Questionnaire" designed for children and adolescents (12-18 year) with JSLE.

## **Study design**

Neuropsychology: Study parameters will be derived from standard tests on intelligence, memory, learning, concentration, executive functions, and rate.

It is a once-only session, and will take about 5 hours, including a 20-30 minute break.

The first Quality of Life Questionnaire will be completed during an outpatient contact. It is ment for validation of the QOL scales. It will take about 30 minutes for the first questionnaire for both patient and parents. The consecutive questionnaires will take about 10 minutes each, and will be repeated during the outpatient visits for 2 years.

## **Study burden and risks**

The extent of the burden of both neuropsychologicla testing and of the Quality of Life questionnaire is minimal, only time investment.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adolescents (12-15 years)

Adolescents (16-17 years)

### Inclusion criteria

.age 12-18 years

.diagnosis of SLE according to ACR criteria

.capable of reading and understanding Dutch language

.informed consent (children < 16 years, also parental informed consent)

### Exclusion criteria

.unable to read or understand the Dutch language

.physically unable to undergo neuropsychological investigation

.refusal of informed consent

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 21-01-2010

Enrollment: 37

Type: Actual

## Ethics review

Approved WMO

Date: 06-07-2009

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## 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	NL25638.041.08

## Study results

Date completed: 01-02-2012

Actual enrolment: 6