

# biomarkers in Systemic Lupus Erythematosus

Published: 13-07-2007

Last updated: 08-05-2024

Construction of a biobank of peripheral blood and skin biopsies from patients with SLE, to evaluate gene polymorphisms, gene expression profiles, new antigens and/or antibodies and to store material for analysis in future in case of newly discovered...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Autoimmune disorders
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON31156

### Source

ToetsingOnline

### Brief title

biomarkers in Systemic Lupus Erythematosus

### Condition

- Autoimmune disorders
- Joint disorders
- Skin and subcutaneous tissue disorders NEC

### Synonym

sle, systemic lupus erythematosus

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

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

## Intervention

**Keyword:** biomarkers, sle, systemic lupus erythematosus

## Outcome measures

### Primary outcome

Main study parameters/endpoints: Construction of a biobank and database of clinical parameters to identify relevant bio-markers.

### Secondary outcome

- Complement C4 polymorphism
- Gene expression profiling

## Study description

### Background summary

Systemic lupus erythematosus (SLE) is a systemic autoimmune disease with a wide range of disease manifestations. Clinical manifestations may differ considerably between patients, ranging from skin rash and arthritis to central nervous system involvement and progressive glomerulonephritis resulting in kidney failure. Very little is known of markers which are associated with disease course, extend and severity of organ involvement, exacerbation frequency and overall disease activity, co-morbidity and mortality. There is a need of identifying bio-markers associated with clinical outcome measures.

### Study objective

Construction of a biobank of peripheral blood and skin biopsies from patients with SLE, to evaluate gene polymorphisms, gene expression profiles, new antigens and/or antibodies and to store material for analysis in future in case of newly discovered relevant antigens, auto-antibodies, gene polymorphisms and gene-expression profiles. The goal is to identify bio-markers associated with clinical manifestations of SLE and identify subgroups of patients according to presence and extend of organ involvement, disease activity, incidence and type of exacerbations, co-morbidity and survival rates.

### Study design

Observational, nested case-control and cohort study.

### **Study burden and risks**

The risk and burden to the subject will be in proportion to the potential value of the research. Research for bio-markers might lead to identification of subgroups, improved diagnosis and prediction of exacerbation and better understanding of the pathogenesis of SLE which could lead to the development of new therapeutic targets or strategies for this disease.

Specified risk and burden: Number of extra institutional visits: none. Number of blood samples: 28 ml (2-3 times a year) and maximum (once a year) 63ml. Skin biopsies: 4-8 skinbiopsies at inclusion or at the time of excacerbation. Risks associated with this study: none.

## **Contacts**

### **Public**

Vrije Universiteit Medisch Centrum

postbus 7057  
1007MB, Amsterdam  
NL

### **Scientific**

Vrije Universiteit Medisch Centrum

postbus 7057  
1007MB, Amsterdam  
NL

## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Diagnosis of SLE according to the 1997 American College of Rheumatology (ACR) revised criteria for the classification of systemic lupus erythematosus criteria for classification of SLE (appendix 1). Age > 18 years. Written informed consent.

## Exclusion criteria

none

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 15-09-2007

Enrollment: 200

Type: Actual

## Ethics review

Approved WMO

Date: 13-07-2007

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 15-03-2018

Application type: Amendment

## 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	NL17200.029.07