

# AMC SLE antibodies.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON20754

### Source

NTR

### Brief title

SLE antibodies

### Health condition

Systemic Lupus Erythematosus, SLE

## Sponsors and support

**Primary sponsor:** AMC amsterdam

**Source(s) of monetary or material Support:** nvt

## Intervention

## Outcome measures

### Primary outcome

The primary goal is to investigate the possibility of generating fully human monoclonal antibodies against type I interferons (IFNs) from B cells of SLE patients.

### Secondary outcome

N/A

## Study description

### Background summary

Blood will be collected from patients with a diagnosis of SLE. The initial study is aimed at generating fully human monoclonal antibodies against type I IFNs from B cells of SLE patients. For this purpose, 50 mL blood from three SLE patients, whose serum contains autoantibodies against type I IFNs, is required.

### Study objective

Interferons (IFNs) are a family of cytokines which have important antiviral and antiproliferative properties. They also play an important role in immunomodulation. Type I IFNs have been implicated in autoimmune diseases, including systemic lupus erythematosus (SLE), where progressive loss of tolerance to nuclear antigens leads to a heterogenous, multisystem disease course characterized by flares and remissions.

The natural occurrence of autoantibodies against type I IFNs has already been described in the early 1980s in patients with SLE, acute viral infections, and malignancies. These findings imply the presence and activation of B cells, which are specific for the indicated cytokine, and it is possible that monoclonal anti-IFN antibodies derived from B cells of SLE patients have clinical value.

### Study design

N/A

### Intervention

No intervention, observational study with invasive measurements.

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

Male and female patients with a diagnosis of SLE and whose serum contains autoantibodies against type I IFNs.

### Exclusion criteria

1. Use of or history of use of B cell-directed therapies;
2. Pregnancy.

## Study design

### Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-05-2011
Enrollment:	10
Type:	Anticipated

## Ethics review

Positive opinion

Date: 23-05-2011

Application type: First submission

## 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
NTR-new	NL2772
NTR-old	NTR2912
Other	METC AMC : 2011-085
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A