AMC SLE antibodies.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	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
Academic Medical Center (AMC), Department of Clinical Immunology and Rheumatology,
P.O. Box 22660
P.P. Tak
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662171
Scientific
Academic Medical Center (AMC), Department of Clinical Immunology and Rheumatology,
P.O. Box 22660
P.P. Tak

Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662171

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