Novel therapeutic targets and biomarkers in patients with Systemic Lupus Erythematosus

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Our aim of the study is investigate IL-7, TSLP and CD30(L) expression in SLE patients en healthy controls to better understand pathogenesis and to find a biomarker that is related to disease activity.

Ethical review	Not approved
Status	Will not start
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON35524

Source
ToetsingOnline

Brief title
New biomarkers for disease activity and treatment in SLE.

Condition

- Autoimmune disorders

Synonym
SLE, 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,Amgen

Intervention

Keyword: activity, Lupus, SLE

Outcome measures

Primary outcome

to study the expression of IL-7, TSLP, CD30L and their receptors in peripheral blood and urine of patients with SLE as compared to healthy controls.

Secondary outcome

To study their correlation with disease activity and immunological parameters. And to assess inflammatory mediators present in serum and urine, and those expressed by T-cells and myeloid cells, to identify biomarkers that reflect disease activity and will help to stratify patients with SLE. The results of the proposed studies may contribute to a future treatment strategy by blockade of some of the investigated inflammatory mediators.
Third objective: Leucocytes will also be stored for DNA isolation, which will be used for analyses of polymorphic sites that might be involved in regulation of transcription of the investigated mol

Study description

Background summary

Systemic lupus erythematosus (SLE) is an auto-immune disease in which the interplay between dendritic cells and T and B cells plays an important role in the immunopathology. IL-7 and IL-7-related cytokine TSLP (thymic stromal lymphopoeitin) are members of the IL-2 family that are able to promote autoimmunity by activation effector T cells and dendritic cells. Activated T cells cause activation of B cells by upregulated expression of costimulatory molecules such as CD30L. This latter molecule is crucially involved in the generation of pathogenic autoantibodies in animal models for SLE.

Despite all this we do not completely understand the pathogenesis of this disease. In relation with that, a biomarker found in pathogenesis that correlates with disease activity is still lacking.

Study objective

Our aim of the study is investigate IL-7, TSLP and CD30(L) expression in SLE patients en healthy controls to better understand pathogenesis and to find a biomarker that is related to disease activity.

Study design

It*s a prospective observational cohort study of SLE-patients
After providing informed consent, clinical data will be gathered including information regarding previous history of lupus activity and involvement, past concomitant medical diseases, past medical history, concomitant medications and a disease acitivty measurement (SLEDAI and BILAG). Additionally 80cc*s of blood will be sampled from which serum and cells for DNA and Phosflow will be isolated and from which miRNA and mRNA will be isolated from the T-cell, monocyte and remaining cell-populations. After that flow-cytometry data from whole blood will be provided to Amgen.
Clinical data and sampled blood will be five times in 1 year (timepoint 0, 3, 6, 9 and-12 months)
The same biomaterials will be collected from 12 healthy controls.

Study burden and risks

There will be no additional risks for the subject. Blood is already taken three monthly in the standard follow-up of SLE patients. Now there will be taken extra blood (80cc) for research in the same setting, so basically no extra venapuncture is needed in the patient group. The healthy controles need a venapuncture but the underlying risks can be neglected.

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

Patients full-filling the ACR criteria for systemic lupus erythematosus

Exclusion criteria

patients with proven other auto-immune disorders
Pregnant women
malignancy

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	62
Type:	Anticipated

Ethics review

Not approved

Date:	31-08-2010
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	NL27823.041.10