Influenza vaccination in patients with systemic lupus erythematosus and Wegener's granulomatosis.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25590

Source
Nationaal Trial Register

Brief title
N/A

Health condition

1. Systemic lupus erythematosus;

2. Wegener's granulomatosis.

Sponsors and support

Primary sponsor: University Medical Center Groningen, the Netherlands
Source(s) of monetary or material Support: 1. University Medical Center Groningen, the Netherlands;
2. J.K. de Cock Foundation, the Netherlands;
3. Solvay Pharmaceuticals, the Netherlands.

Intervention

Outcome measures

Primary outcome

Antibody response to vaccination:
seroprotection rate, fourfold titre rises and geometric mean titres.

Secondary outcome

1. safety: changes in disease activity in terms of SLEDAI (systemic lupus erythematosus) or BVAS (Wegener's granulomatosis).

2. Effect of immunosuppressive drugs on antibody responses to vaccination

3. cell-mediated responses to influenza (vaccination)

Study description

Background summary

Influenza vaccination in patients with systemic lupus erythematosus (SLE) and Wegener's granulomatosis (WG) seems indicated, as they are at increased risk for infections and have a higher risk of morbidity and mortality following influenza infection. However, questions regarding safety and efficacy of vaccination remain.

In this study we will address the questions concerning safety and immunogenicity of influenza vaccination in our (immuno-suppressed) cohorts of SLE and WG patients. Patients with different immuno-suppressive regimes will be vaccinated and disease activity and antibody response will be monitored thereafter.

Patients will be randomized to receive either a vaccination or to participate as patient control. Furthermore a group of healthy controls will be vaccinated. Follow-up will be at 1 month and 3-4 months following vaccination.

Primary outcomes is the antibody response to vaccination, secondary outcomes are disease

activity as measured by disease activity indexes and cell-mediated immune responses to influenza.

Study objective

1. a. Does influenza vaccination in SLE and Wegener patients result in a decreased humoral immune response compared to healthy age-matched controls?;

b. Does influenza vaccination in SLE and Wegener patients result in a decreased cellular immune respons compared to healthy age-matched controls?;

c. Do different immuno-suppressive therapies in these patients influence the immune responses after vaccination?;

2. Does influenza vaccination in SLE and Wegener patients increase disease activity?

Study design

t = 0

t = 1 month

t = 3-4 months

Intervention

Influenza vaccination.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients have to fulfil international disease criteria of SLE or WG;

2. quiescent disease, defined as SLEDAI under 6 or BVAS under 2;

3. informed consent.

Exclusion criteria

SLE patients are not eligible for the study in case of:

1. active disease, defined as SLEDAI >5;

2. a yearly influenza vaccination is concerned mandatory by the patient's physician;

3. use of prednisone >30 mg/day;

4. pregnancy;

5. no informed consent.

WG patients are not eligible for the study in case of:

1. active disease, defined as BVAS >1;

2. a yearly influenza vaccination is concerned mandatory by the patient's physician;

3. use of prednisone >30 mg/day;

4. use of cyclofosfamide >100 mg/day;

5. pregnancy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2005
Enrollment:	240
Type:	Actual

Ethics review

Positive opinion

Date:	14-11-2007
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	NL1096
NTR-old	NTR1130
Other	Medical Ethics Committee - University Medical Center Groningen : 2005-147
ISRCTN	Wordt niet aangevraagd/retrospectief onderzoek

Study results

Summary results
Ann Rheum Dis. 2008 Jul 14. [Epub ahead of print].