Does booster influenza vaccination improve vaccination efficacy in patients with quiescent systemic lupus erythematosus?

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To determine whether a second, booster, influenza vaccination leads to a higher seroprotection rate in SLE patients, as compared to a single vaccination.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON31124

Source
ToetsingOnline

Brief title
n.v.t.

Condition

- Autoimmune disorders

Synonym
systemische lupus erythematosus; lupus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,JK de Cock

Stichting,Solvay Pharmaceuticals

Intervention

Keyword: booster, influenza vaccination, second, systemic lupus erythematosus

Outcome measures

Primary outcome

Seroprotection rate (the percentage of SLE patients with a titre equal to or

greater than 40 against all three vaccine strains) in SLE patients after two

influenza vaccinations as compared to a single vaccination.

Secondary outcome

1. Seroconversions and fourfold titre rises after 4 weeks and after 8 weeks.

2. Geometric mean titres after four weeks and after 8 weeks

Study description

Background summary

Systemic lupus erythematosus (SLE) is an autoimmune disease, patients are often treated with immunosuppressive drugs to control disease activity. This causes patients to be susceptible for infections, like influenza. Former research showed influenza vaccination to be safe in SLE, however fewer patients reached protective titres as compared to healthy controls. It is desirable to increase this seroprotection rate. A second, booster vaccination, administered 4 weeks after the first vaccination is a possible approach to achief a higher seroprotection rate.

Study objective

To determine whether a second, booster, influenza vaccination leads to a higher seroprotection rate in SLE patients, as compared to a single vaccination.

Study design

Fifty-two SLE patients and 30 healthy controls will be included. Patients will receive an influenza vaccination in October - December 2007. Four weeks later

a second, booster, vaccination will be given. Healthy controls will receive a single vaccination, in October - December 2007. Evaluation of titres will be done before vaccination and four weeks following the first vaccination. In patients a second titre evaluation will be done four weeks after the second vaccination.

Intervention

Administration of a trivalent subunit influenza vaccine: Influvac. In SLE patients this vaccine will be given for a second time, four weeks after the first vaccination.

Study burden and risks

Patients
Receiving an influenza vaccination gives SLE patients a good chance to have sufficient protection against influenza in the following influenza season. The non-regular outpatient visit after 28 days is a burden, furthermore a total of 30 ml of blood will be drawn. The adverse effects of influenza vaccination are usually mild, though SLE patients have to experience an extra time.

Healthy controls
Influenza vaccination will be done as part of the hospital campaign to vaccinate health care workers. Therefore this is not an extra burden. Two times 10 ml of blood will be drawn, which is considered as a small burden.

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
- patients have to fulfil international disease criteria of SLE
- quiescent disease, defined as SLEDAI <=5
- informed consent;Healthy controls
- informed consent

Exclusion criteria

Patients
- active disease, defined as SLEDAI >5
- use of prednisone >30 mg/day
- pregnancy
- malignancy
- no informed consent;Healthy controls
- use of immunosuppressives
- malignancy
- pregnancy
- no informed consent

Study design

Design

Study type: Interventional

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-09-2007
Enrollment:	82
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	influvac
Generic name:	influenza vaccin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	24-08-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
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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
EudraCT	EUCTR2007-004579-21-NL
CCMO	NL18929.042.07