Influenza, pneumococcal and hepatitis B vaccination in patients with rheumatic autoimmune disorders treated with immunosuppressants.

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

Summary

ID

NL-OMON31399

Source
ToetsingOnline

Brief title
n.v.t.

Condition

- Autoimmune disorders
- Joint disorders

Synonym
rheumatic autoimmune diseases

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: immunosuppressant, response, rheumatic autoimmune disorders, vaccination

Outcome measures

Primary outcome

Increase in titer of:

- Haemagglutination inhibition test for influenza

- ELISA for pneumococcal

- ELISA for hepatitis B

Secondary outcome

- Potential adverse events

- Disease activity

Study description

Background summary

Patients with rheumatic autoimmune disorders often require therapy with agents that potentially compromise the immune response and subsequently increase the risk for morbidity and mortality due to infections. Influenza and pneumococcal vaccination is therefore indicated in these patients, but often forgotten.
The disease itself and immunosuppressive therapy may influence the response to vaccination. However, little is known about this influence. Therefore, in this study we want to investigate the response to vaccination during immunosuppressive therapy. This may lead do adjustments to the current vaccination policy.

Study objective

The primary goal of this study is to evaluate the efficacy and safety of

influenza, pneumococcal and hepatitis B vaccination in patients with rheumatic autoimmune diseases treated with immunosuppressive therapy compared to healthy controls.
The secondary goal of this study is to evaluate the efficacy of a two-dose vaccination regimen of influenza vaccination in patients with rheumatic autoimmune diseases treated with immunosuppressive therapy.

Study design

In this open-label study the response to influenza, pneumococcal and hepatitis B vaccination will be investigated in patients with rheumatic autoimmune diseases treated with immunosuppressive therapy. This response will be compared with the response to these vaccinations in healthy controls. The response to a second influenza vaccination will also be examined in the patients. The response to influenza vaccination is T cell dependent and the response to pneumococcal vaccination is T cell independent with stimulation of B cells. A part of the patients with rheumatic autoimmune disorders will have received these vaccinations prior to start of this study. Hepatitis B vaccination is chosen to investigate the response to a de-novo antigen. The response to influenza vaccination will be assessed by a haemagglutination inhibition test. The response to pneumococcal and hepatitis B vaccination will be assessed by standard ELISAs (enzyme-linked immunosorbent assays). In total 90 patients will be included in the study: 30 treated with rituximab, 30 treated with TNFα blocking agents and 30 treated with traditional DMARDs. The responses of these patients will be compared with the response to the same vaccinations in 30 healthy controls.

Study burden and risks

Burden patients:
- Drawing of extra blood samples (in total 4 times, total 40 ml blood).
- Extra time investment (5 times of 30 minutes = 2,5 hours).
- Extra hospital visits (about 2-3 times).

Burden healthy controls:
- Drawing of extra blood samples (in total 2 times, total 20 ml blood).
- Extra time investment (2 times 15 minutes = 0,5 hour).
- Extra hospital visit (1 time).

Risks:
- Venapunction: adverse events are rare.
- Intramuscular injections: most people will not experience adverse events. Mild local reactions at the injection site may occur (including pain, mild redness, swelling, bruises and a stiff arm). Sometimes systemic side effects occur, including fever, chills, sweating, malaise, tiredness and muscle or joint pain. The complaints often resolve within 1 to 2 days without

intervention. Serious side effects are rare.

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

In general: willing to give written informed consent.
Per group:
1. Patients with rheumatic autoimmune diseases, including rheumatoid arthritis, poly or dermatomyositis, systemic lupus erythematosus, Sjögren*s syndrome, treated with rituximab within 3-9 months prior to start of the study with or without concomitant treatment with traditional DMARDs and/or corticosteroids.
2. Patients with rheumatic autoimmune diseases, including rheumatoid arthritis, poly or dermatomyositis, systemic lupus erythematosus, Sjögren*s syndrome, treated with TNFα blocking agents as single therapy or combined with DMARDs and/or corticosteroids on stable

therapy of 3 or more months.
3. Patients with rheumatic autoimmune disease, including rheumatoid arthritis, poly or dermatomyositis, systemic lupus erythematosus, Sjögren*s syndrome, on stable therapy with only traditional DMARDs and/or corticosteroids for 3 or more months.
4. Age and gender matched healthy controls

Exclusion criteria

- Age under 18 years
- No informed consent
- Pregnancy
- History of vaccination allergy
- Known allergy to egg products
- Patients known with positive hepatitis B serology

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	01-10-2007
Enrollment:	120
Type:	Anticipated

Ethics review

Not approved

Date:	22-10-2007
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2007-005309-23-NL
CCMO	NL19268.000.07