Influenza, pneumococcal and hepatitis B vaccination in patients with rheumatic autoimmune diseases treated with immunosuppressive therapy

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

Summary

ID

NL-OMON32031

Source
ToetsingOnline

Brief title
Vaccinations in rheumatic autoimmune diseases

Condition

- Autoimmune disorders

Synonym
Rheuma., 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: immunosuppressive therapy, response, rheumatic autoimmune disease, vaccination

Outcome measures

Primary outcome

The main study endpoints are the humoral responses to influenza, pneumococcal and hepatitis B vaccination. The humoral responses will be analysed using the response rates and the geometric mean titres (GMT).

For influenza, seroprotection rates are defined as a serum HI titre >=1/40.

Seroconversion rates are defined as a 4 fold rise in serum HI titre or serum HI titre changing from <1/40 to >=40.

The humoral response to pneumococcal vaccination is defined according to the WHO as a >= 2 fold increase in antibody titers and a postvaccinationtiter of >= 0.35 ug/ml.

Response to hepatitis B vaccination is defined as an antibody titre higher than 10 IU/l after vaccination.

Secondary outcome

The safety of influenza, pneumococcal and hepatitis B vaccination will be assessed by reporting adverse events on an adverse events registration form.

The effects of influenza, pneumococcal and hepatitis B vaccination on disease activity of the rheumatic autoimmune diseases will be assessed by the DAS28 score. The Health Assessment Questionnaire (HAQ) will be taken to assess disability.

Study description

Background summary

Patients with rheumatic autoimmune diseases have an increased risk for morbidity and mortality due to infections. The use of immunosuppressive therapy further increases this risk. To prevent morbidity and mortality due to infections, patients may be vaccinated against several antigens. However, little is known about the influence of immunosuppressive therapy on the ability to respond to vaccinations, especially the influence of biological agents including TNFα blocking agents, B cell depleting therapy or co-stimulation blocking therapy.

Study objective

The primary objective of this study is to evaluate the humoral response to influenza, pneumococcal and hepatitis B vaccination in patients with rheumatic autoimmune diseases (reumatoide artritis and poly- dermato-myositis) treated with immunosuppressive therapy. The secondary objectives are to evaluate the safety of these vaccinations and to evaluate the humoral response to a two-dose vaccination regimen of influenza vaccination in patients with rheumatic autoimmune diseases treated with immunosuppressive therapy.

Study design

This is a 28 week single centre study. Patients will receive two influenza vaccinations at baseline and week 4, a pneumococcal vaccination at baseline and three hepatitis B vaccinations at baseline, week 4 and week 24.
The humoral response to vaccination will be assessed at week 4 for the influenza and pneumococcal vaccination and at week 8 for the second influenza vaccination and at week 28 for the hepatitis B vaccinations.

Intervention

Patients will receive two influenza vaccinations (Influvac, 2008-2009, Solvay Pharma BV), one pneumococcal vaccination (Pneumovax 23, Aventis Pasteur MSD) and three hepatitis B vaccinations (HBVAXPRO 10 microgram/ml, Sanofi Pasteur MSD).

Study burden and risks

Patients will have six study visits in total. Patients will receive six vaccinations: three at baseline, two at week 4 and one at week 24. Blood samples (10 ml) to analyse the humoral responses will be taken at baseline and at week 4, 8, 24 and 28. At baseline one blood sample (5 ml) will be taken for

hepatitis B screening. At baseline, week 4, 8, 24 and 28 blood samples (10 ml) will be taken to assess the ESR and CRP. At each visit, except at screening, disease activity will be assessed using the DAS28 score. The functional disability will be assessed using a questionnaire (HAQ). Patients will receive an adverse events registration form at each study visit to assess safety.

Participation in this study will contribute to more knowledge about the response to vaccination in patients with rheumatic autoimmune diseases treated with immunosuppressive therapy. The vaccinations are aimed at protection against infections and against infectious complications. If the vaccinations in this study are effective, the influenza vaccination will protect for one year, the pneumococcal vaccination for about five years and the hepatitis B vaccination for at least 20 years. Adverse events against vaccinations are not different in patients and healthy controls. They are mostly mild and may consist of local injection site reactions, including redness, swelling, pain, bruising or stiffness of the arm. Sometimes, adverse events may consist of short flu-like reactions such as fever, sweating, shivering, headache, tiredness or muscle or joint pain. Severe allergic reactions are very rare. Blood samples will be collected from a vein in the arm. At the injection side bruising may occur. Other adverse events are very rare with this procedure.

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

All patients and healthy controls must be:
1. 35-75 years of age
2. BMI >= 18.5
3. Willing to give written informed consent
4. Diagnosed with rheumatoid arthritis according to the 1987-revised ACR-classification criteria or poly or dermatomyositis according to the criteria of Bohan and Peter.

Exclusion criteria

Patients and controls are excluded from the study if he/she meets any of the following criteria:
1. Pregnancy
2. History of vaccination allergy
3. Known allergy to egg products
4. Positive hepatitis B serologyor denial to be tested or informed over the hepatitis B serology results
5. Rheumatic autoimmune disorder other than rheumatoid arthritis or poly or dermatomyositis

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2008
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	18-09-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	23-09-2008
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	EUCTR2008-001282-28-NL
CCMO	NL22237.000.08