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

Gepubliceerd: 14-11-2007 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25590

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

1. Systemic lupus erythematosus;

2. Wegener's granulomatosis.

Ondersteuning

Primaire sponsor: University Medical Center Groningen, the Netherlands
Overige ondersteuning: 1. University Medical Center Groningen, the Netherlands;
2. J.K. de Cock Foundation, the Netherlands;
3. Solvay Pharmaceuticals, the Netherlands.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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?

Onderzoeksopzet

t = 0

t = 1 month

t = 3-4 months

Onderzoeksproduct en/of interventie

Influenza vaccination.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2005
Aantal proefpersonen:	240
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-11-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1096
NTR-old	NTR1130
Ander register	Medical Ethics Committee - University Medical Center Groningen : 2005-147
ISRCTN	Wordt niet aangevraagd/retrospectief onderzoek

Resultaten

Samenvatting resultaten
Ann Rheum Dis. 2008 Jul 14. [Epub ahead of print].