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

Gepubliceerd: 19-11-2007 Laatst bijgewerkt: 13-12-2022

SLE patients show a decreased humoral immune response to influenza vaccination, as compared to healthy controls. Furthermore the use of immunosuppressives is of influence on vaccination immunogenicity, it has been demonstrated that the use of drugs...

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

Samenvatting

ID

NL-OMON20800

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

1. Systemic lupus erythematosus (SLE);

2. influenza vaccination;

3. booster;

4. antibody response.

Ondersteuning

Primaire sponsor: University Medical Center Groningen (UMCG)
P.O. Box 30001

9700 RB
Groningen
The Netherlands
+31 (0)50 3616161
Overige ondersteuning: Solvay Pharmaceuticals GMBH
Weesp, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

In this study, it will be assessed whether a second, booster, influenza vaccination leads to a higher seroprotection rate in SLE patients, as compared to a single vaccination.

Doel van het onderzoek

SLE patients show a decreased humoral immune response to influenza vaccination, as compared to healthy controls. Furthermore the use of immunosuppressives is of influence on vaccination immunogenicity, it has been demonstrated that the use of drugs like corticosteroids, azathioprine, and cyclosporin hampers the humoral immune response, reflected by a decreased antibody response after vaccination.

In liver transplant recipients a decreased humoral immune response to influenza vaccination was found as well. A second, booster, influenza vaccination improved the humoral immune response.

In this study we will investigate whether a second, booster, influenza vaccination improves the immune response in SLE patients with quiescent disease. Patients with different immunosuppressive regimes will be vaccinated and disease activity and antibody response will be monitored thereafter.

Onderzoeksopzet

1. inclusion, t = 0;

2. t = 4 weeks;

3. t = 8 weeks (only for SLE patients).

Onderzoeksproduct en/of interventie

Influenza vaccination, followed by a second influenza vaccination in SLE patients after 4 weeks.

Contactpersonen

Publiek

Department of Internal Medicine, Division of Clinical Immunology
University Medical Center Groningen, University of Groningen
PO Box 30.001
A. Holvast
Groningen 9700 RB
The Netherlands
31) 50-3612945,

Wetenschappelijk

Department of Internal Medicine, Division of Clinical Immunology
University Medical Center Groningen, University of Groningen
PO Box 30.001
A. Holvast
Groningen 9700 RB

The Netherlands
31) 50-3612945,

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients:

1. patients have to fulfil international disease criteria of SLE;

2. quiescent disease, defined as SLEDAI ¡Ü5;

3. informed consent;

Healthy controls:

1. informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients:

1. active disease, defined as SLEDAI >5;

2. use of prednisone >30 mg/day;

3. pregnancy;

4. malignancy;

5. no informed consent.

Healthy controls:

1. use of immunosuppressives;

2. malignancy;

3. pregnancy;

4. no informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	27-09-2007
Aantal proefpersonen:	82
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	19-11-2007
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	NL1112
NTR-old	NTR1147
Ander register	Medical Ethics Committee University Medical Center Groningen : 2007/172
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A