

SEVRA-TRIAL Safety and efficacy of vaccination with T cell-dependent and T cell-independent primary and recall antigens in patients with rheumatoid arthritis treated with anti TNF- α antibodies (adalimumab) and anti B cell therapy (Rituximab).

Gepubliceerd: 18-10-2007 Laatste bijgewerkt: 18-08-2022

To assess the effect of adalimumab (anti-TNF alpha) and rituximab (anti- B cell) therapy on the safety and efficacy of vaccination with T cell-dependent and T cell-independent primary and recall antigens.

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

Samenvatting

ID

NL-OMON25723

Bron

NTR

Verkorte titel

SEVRA

Aandoening

Rheumatoid arthritis.

Ondersteuning

Primaire sponsor: Philip Remans, MD, PhD, Division of Clinical Immunology and Rheumatology, Hans Schipper, MD, PhD, Department of Internal Medicine, Theo Out, PhD,

laboratory of Medical Immunology, René Lutter, PhD, Department of Experimental immunology, Ruth klaasen, MD, Division of Clinical Immunology and Rheumatology, Danielle Gerlag, MD, Division of Clinical Immunology and Rheumatology, Paul P. Tak, MD, PhD, Professor of Medicine.

Overige ondersteuning: Academic medical center, Div of clinical rheumatology Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage of patients with positive response to vaccination prior and post adalimumab or rituximab therapy, and measured 4 weeks after administration of the vaccins. Response is defined as a 2-fold increase in antibody levels to the administered antigens or as an absolute change in specific antibody of 1 g/mL, or seroconversion in patients with a non-protective baseline level of antibodies ($<1/40$).

Toelichting onderzoek

Achtergrond van het onderzoek

Evaluating the effect of anti TNF alpha(adalimumab) therapy and anti B cell therapy (Rituximab) on the safety and efficacy of vaccination with T cell-dependent and T cell-independent primary and recall antigens in DMARD refractory RA patients.

Doel van het onderzoek

To assess the effect of adalimumab (anti-TNF alpha) and rituximab (anti- B cell) therapy on the safety and efficacy of vaccination with T cell-dependent and T cell-independent primary and recall antigens.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Vaccinatie met KLH, Tetanus vaccine, Hepatitis A vaccine, pneumo 23, Mencevax ACWY en poliomyelitisvaccin.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Able and willing to give written informed consent;
2. A diagnosed according to the revised 1987 criteria of the American College of Rheumatology (ACR) for at least 3 months;
3. Age 18-85 years;
4. Eligible for anti-TNF á therapy (according to the Dutch guidelines) or eligible for rituximab therapy;
5. Use of concurrent dmard therapy is allowed, provided the dose and frequency have been stable for at least 28 days. Subjects may be taking nonsteroidal anti-inflammatory drugs, provided the dose and frequency have been stable for at least 28 days. Subjects may be receiving prednisone therapy $\leq$ 10 mg/day provided that the dosage has been stable for at least 2 months prior to entry.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A positive PPD skin test (> 4 mm induration);
2. Pregnancy;
3. Breastfeeding;
4. A history of or current acute inflammatory joint disease of different origin e.g. mixed connective tissue disease, seronegative spondylarthropathy, psoriatic arthritis, Reiter's syndrome, systemic lupus erythematosus or any arthritis with onset prior to age 16 years;
5. Acute major trauma;
6. Therapy within the previous 60 days with: any experimental drug, alkylating agents, e.g. cyclophosphamide, chlorambucil, monoclonal antibodies (including infliximab and etanercept), growth factors, or other cytokines;
7. Therapy within the previous 28 days with: parenteral or intra-articular corticoid injections, oral corticosteroid therapy exceeding a prednisone equivalent of 10 mg daily;
8. HIV infection;
9. History of severe allergic or anaphylactic reactions to vaccines;
10. Vaccination with KLH, Pneumovax, Meningovax, Polio or tetanus toxoid in the past 12 months;
11. Fever (orally measured > 38 °C), chronic infections or infections requiring anti-microbial therapy Other active medical conditions such as inflammatory bowel disease, bleeding diathesis, or severe unstable diabetes mellitus;
12. Manifest cardiac failure (stage III or IV according to NYHA classification);
13. Progressive fatal disease/terminal illness;
14. Congenital or acquired (known HIV-positive status) immunodeficiency;
15. History of lymphoproliferative disease or treatment with total lymphoid irradiation;
16. White cell count less than $3.5 \times 10^9/l$;
17. Platelet count less than $100 \times 10^9/l$;
18. Haemoglobin of less than 5.3 mmol/l;

19. Body weight of less than 45 kg;
20. History of drug or alcohol abuse;
21. Any concomitant medical condition which would in the investigator's opinion compromise the patient's ability to tolerate, absorb, metabolize or excrete the study medication;
22. Inability to give informed consent;
23. Mental condition rendering the patient unable to understand the nature, scope and possible consequences of the study and/or evidence of an uncooperative attitude.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-05-2007
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	18-10-2007
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	NL1055
NTR-old	NTR1088
Ander register	MEC AMC : 06/261
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A