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-á antibodies (adalimumab) and anti B cell therapy (Rituximab).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25723

Source
NTR

Brief title
SEVRA

Health condition

Rheumatoid arthritis.

Sponsors and support

Primary sponsor: Philip Remans, MD,PhD, Division of Clinical Immunology and Rheumatology, Hans Schipper, MD, PhD, Department of Internal Medicin, 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.
Source(s) of monetary or material Support: Academic medical center, Div of clinical rheumatology Amsterdam

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

To analyse the effect of vaccination on RA disease parameters and the influence of adalimumab and rituximab therapy on T and B cell response after vaccination, as well as the relation T-B cell response. This will be done by analyzing T and B cell subsets, T cell cytokine production to specific antibody stimulus measured by elispot and immunoglobuline subtypes.

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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 10 mg/day provided that the dosage has been stable for at least 2 months prior to entry.

Exclusion criteria

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 x 109/l;

17. Platelet count less than 100 x 109/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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2007
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-10-2007
Application type:	First submission

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
NTR-new	NL1055
NTR-old	NTR1088
Other	MEC AMC : 06/261
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A