ESRA onderzoek.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28264

Source
NTR

Brief title
ESRA trial

Health condition

RA, reumatoide artritis, Rheumatoid Arthritis

Sponsors and support

Primary sponsor: Academisch Medisch Centrum div. Immunology and Rheumatology
Source(s) of monetary or material Support: Academisch Medisch Centrum div. Immunology and Rheumatology

Intervention

Outcome measures

Primary outcome

The coprimary immunogenicity end points are the proportion of subjects with antibody titers of 1:40 or more on hemagglutination-inhibition (HI) assay, the proportion of subjects with either seroconversion or a significant increase in antibody titer (more than 4-fold), and the factor increase in the geometric mean titer (GMT).

Secondary outcome

N/A

Study description

Background summary

N/A

Study objective

Since previous studies suggest that an influenza vaccination is probably less or even not effective in rituximab treated RA patients, we want to investigate if this also holds true for this new vaccine against the H1N1 virus.

Study design

Prior to vaccine administration and 4 weeks after second vaccination.

Intervention

All patients and volunteers will receive an A/H1N1 vaccine according to the National Guidelines. The administration of the vaccine will be coordinated by the Dutch government. Before the first vaccination and 4 weeks after the second vaccination serum samples will be collected and B-lymphocyte counts will be assessed. Functional tests on the isolated B- and T lymphocytes will be performed.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria for group A:

1. Able and willing to give written informed consent;

2. RA 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. Been treated with rituximab and B-cell depleted (<0.1x109/L).

Inclusion criteria for group B:

1. Able and willing to give written informed consent;

2. RA diagnosed according to the revised 1987 criteria of the American College of Rheumatology (ACR) for at least 3 months;

3. Treatment with methotrexate;

4. Age 18-85 years.

Inclusion criteria for healthy volunteers:

1. Able and willing to give written informed consent;

2. Age 18-85 years.

Exclusion criteria

Exclusion criteria for groups A and B:

1. Therapy within the previous 60 days with:

A. Any experimental drug;

B. Monoclonal antibodies (for group A: other than rituximab);

C. Growth factors;

D. Other anti-cytokines.

2. Therapy within the previous 28 days with:

A. Parenteral or intra-articular corticoid injections;

B. Oral corticosteroid therapy exceeding a prednisone equivalent of 10 mg daily.

3. Chronic infections or infections requiring anti-microbial therapy. Other active medical conditions such as inflammatory bowel disease, bleeding diathesis, or severe unstable diabetes mellitus;

4. Mental condition rendering the patient unable to understand the nature, scope and possible consequences of the study and/or evidence of an uncooperative attitude.

Exclusion criteria for healthy volunteers:

1. Any clinically significant medical condition.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	16-11-2009
Enrollment:	45
Type:	Actual

Ethics review

Positive opinion Date:	02-08-2010
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	NL2338
NTR-old	NTR2445
Other	MEC AMC / EUdraCT : 09/312 / 2009-016789-10 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A