ESRA onderzoek.

Gepubliceerd: 02-08-2010 Laatst bijgewerkt: 18-08-2022

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.

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

Samenvatting

ID

NL-OMON28264

Bron
NTR

Verkorte titel
ESRA trial

Aandoening

RA, reumatoide artritis, Rheumatoid Arthritis

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum div. Immunology and Rheumatology
Overige ondersteuning: Academisch Medisch Centrum div. Immunology and Rheumatology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

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.

Onderzoeksopzet

Prior to vaccine administration and 4 weeks after second vaccination.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Academic Medical Center (AMC), Department of Clinical Immunology and Rheumatology,
P.O. Box 22660
P.P. Tak
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662171

Wetenschappelijk

Academic Medical Center (AMC), Department of Clinical Immunology and Rheumatology,
P.O. Box 22660

P.P. Tak
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5662171

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	16-11-2009
Aantal proefpersonen:	45
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	02-08-2010
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	NL2338
NTR-old	NTR2445
Ander register	MEC AMC / EUdraCT : 09/312 / 2009-016789-10 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A