# An open-label pilot study on the effects of trivalent inactivated influenza vaccination (Influvac®) in rheumatoid arthritis patients treated with rituximab.

No registrations found.

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

## Summary

### ID

NL-OMON25369

**Source**
NTR

**Brief title**
N/A

**Health condition**

1. Rheumatoid Arthritis (NLD: reumatoide artritis);

2. Anti-CD20;

3. Rituximab;

4. Influenza vaccination (NLD: Influenza vaccinatie);

5. Humorale immune response (NLD: humorale immuunrespons);

6. Hemagglutinin inhibition assay (NLD: hemagglutinatie remmingstest);

7. Cellular immune response (NLD: cellulaire imuuunrespons);

8. FACS/ICS;

9. ELIspot.

## Sponsors and support

**Primary sponsor:** UMCG
**Source(s) of monetary or material Support:** Johannes Cornelis de Cock-stichting

## Intervention

## Outcome measures

### Primary outcome

Immune response one to four weeks after vaccination, humoral and cellular.

### Secondary outcome

1. RA-activity (DAS-28);

2. Side effects influenza vaccination.

# Study description

### Background summary

Rituximab (anti-CD20) is a promising new drug in the treatment of rheumatoid arthritis (RA) patients. After treatment peripheral B cell depletion occurs rapidly and sustains for 6-9 months. Therefore dampened humoral and/or cellular immune responses in RA patients might be expected, although increased infection rates have not been shown in relation to treatment with rituximab.

Because patients on immunosuppressive drugs are at increased risk for complicated influenza, national guidelines advice to immunize these patients annually for influenza. To our knowledge, no studies have been published on efficacy of vaccination against influenza virus with the currently used subunit vaccines in RA-patients treated with rituximab.
In this context, of patients who are presumably unable to produce protective antibodies due to depletion of peripheral B-cells, but possibly capable of eliciting protective T-cell responses to influenza virus, we designed a study protocol to determine the humoral and cellular immune responses following influenza vaccination in RA patients treated with rituximab.

Humoral and T-cell responses will be determined in RA-patient at different timepoints after single or multiple cycles of rituximab application at three time points following vaccination with influenza virus subunit vaccine for the season 2007-2008, and compared with the

responses measured in healthy controls.

The two questions to be answered are:

1. Is vaccination with trivalent inactivated influenza vaccine in RA patients treated with rituximab useful; do these patients elicit adequate humoral and cellular T-cell responses after influenza vaccination?;

2. Are effects of single or multiple courses of rituximab long lasting; is the response to influenza vaccination after B cell repopulation affected?

### Study objective

Patients with rheumatoid arthritis (RA) treated with rituximab have reduced humoral and cellular immune responses to vaccination with trivalent inactivated influenzavaccine.

### Study design

1. 0: base line routine labs, humoral and cellular immune response, RA-activity; vaccination;

2. 7: routine labs, cellular immune response, RA-activity and side effects one week after immunization;

3. 21-28: routine labs, humoral and cellular immune response and RA-activity three to four weeks after immunization.

### Intervention

Influenza vaccination.

## Contacts

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# Eligibility criteria

## Inclusion criteria

1. Patients have to fulfil the diagnostic criteria for RA as defined by the ACR9;

2. group I: treatment with rituximab (according to RA scheme), in combination with methotrexate, started 4 weeks before inclusion;

3. group II: treatment with rituximab (according to RA scheme), in combination with methotrexate, started 6-9 months before inclusion;

4. group III: second or third treatment with rituximab (according to RA scheme), in combination with methotrexate, started 4 weeks before inclusion;

5. group IV: treatment with monotherapy methotrexate (minimal dose 10 mg/week);

6. informed consent.

## Exclusion criteria

1. Age under 18 years;

2. current infection, defined as fever in combination with clinical focal signs of infection and the need for therapeutic antibiotic treatment;

3. pregnancy;

4. malignancy;

5. known allergy to or former severe reaction following Influvac®.

# Study design

### Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-10-2007 |
| Enrollment: | 70 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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|---|---|
| Date: | 14-11-2007 |
| 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 | NL1102 |

| Register | ID |
| --- | --- |
| NTR-old | NTR1137 |
| Other | : METc2007/100 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Study results

**Summary results**
N/A