# COBRA-light study, an open randomised trial comparing a modified COBRA therapy with the COBRA therapy according to BeSt in early rheumatoid arthritis.

No registrations found.

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

## Summary

### ID

NL-OMON26545

**Source**
NTR

**Brief title**
COBRA-light

**Health condition**

Rheumatoid arthritis

### Sponsors and support

**Primary sponsor:** VU medical centre (VUmc) Amsterdam, Department of Rheumatology
**Source(s) of monetary or material Support:** TIPharma, Wyeth

### Intervention

### Outcome measures

**Primary outcome**

Difference in delta DAS compared at baseline between the both treatment strategies after 6 months.

### Secondary outcome

-Difference in delta DAS compared with baseline between the treatmentstrategies after 12 months - % patients with ACR 20, 50, 70 response - Low disease status (DAS 44 <2,4) - HAQ - delta Sharp van der Heijde score - % patients with radiological remission - number of patients started with anti-TNF - patients in clinical remission after six or twelve months will be tested for subclinical synovitis with a PETscan, ultrasound and MRI
Tertiary outcome: bone and cartilage metabolism, cardiovascular and endocrine parameters

## Study description

### Background summary

An open, randomised trial comparing two treatment strategies, COBRA and a modified COBRA-schedule, in patients with early RA. The secondary aim of this trial is to study the side effects of glucocorticosteroids on bone-and cartilage metabolism, insulin resistance and metabolic syndrome. A total of 160 patients will be included and treated according to the randomised treatment strategy untill week 52 and followed-up untill week 104.

### Study objective

Early, aggressive treatment of rheumatoid arthritis with DMARDs has been proven to lower disease activity and suppress radiologic progression. Moreover, combination therapy is shown to be superior to monotherapy. The COBRA therapy is effective in several trials, and the positive effect on radiologic progression sustained over time. In a recent trial (BeSt) comparing different treatment strategies the COBRA therapy and initial therapy with Infliximab (a TNF-blocker) were equally effective in improving functional ability and preventing radiographic damage. Apparently most rheumatologists and or patients have resistance in prescribing this therapy.

### Study design

At baseline patients will be included and extensively examined. At decision moments, eg weeks 13, 26, 39, 52, 78 and 104, an independent research nurse will perform an assessment of the disease activity. This will be followed by a visit with the treating physician.

### Intervention

The study design randomizes the two treatment strategies, ie COBRA or a modified COBRA schedule.

In the first year patients will be seen frequently in order to follow disease-activity, side effects and
cardiovascular parameters. In the first year patients will be seen at 2, 4, 8, 13, 26, 39 en 52 weeks. Treatment will be adjusted according to the DAS44 score. In the
follow-up period of the second year patients will be seen every six months.

## Contacts

**Public**
VU Medical Center
depatment of rheumatology 4a-42
Boelelaan 1117
W.F. Lems
Amsterdam 1081 HV
The Netherlands
+31 20-4443432
**Scientific**
VU Medical Center
depatment of rheumatology 4a-42
Boelelaan 1117
W.F. Lems
Amsterdam 1081 HV
The Netherlands
+31 20-4443432

## Eligibility criteria

### Inclusion criteria

1. Active RA according to ACR criteria,

2. >6 swollen joints or >6 painful joints,

3. Disease duration < 2jr,

4. ESR > 28mm,

5. VAS > 20,

6. Age > 18 years

### Exclusion criteria

1. Prior treatment DMARDs (except hydroxychloroquine).

2. Insulin-dependent Diabetes mellitus.

3. Uncontrollable non-insuline dependent diabetes mellitus.

4. Heart failure NYHA class 3-4.

5. Uncontrollable hypertension.

6. ALAT/ASAT > 3 times normal values.

7.Reduced renal function (serum creat > 15mcmol).

8. Contra-indications for methotrexate, sulphasalazine or prednisolone.

9. Indications of probable tuberculosis

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-02-2008 |
| Enrollment: | 160 |
| Type: | Anticipated |

# Ethics review

Positive opinion

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|---|---|
| Date: | 28-02-2008 |
| 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 | NL1168 |
| NTR-old | NTR1213 |
| Other | METC : 2007/150 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Study results

**Summary results**
N/A