

# Anti-tumour necrosis factor (anti-TNF) therapy over two years increases body fat mass in early rheumatoid arthritis

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<b>Registration date</b> 06/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 06/04/2011	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Inga-Lill Engvall

**Contact details**  
Department of Rheumatology, R92  
Karolinska University Hospital  
Huddinge  
Stockholm  
Sweden  
14186

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

Anti-tumour necrosis factor therapy increases body fat mass in early rheumatoid arthritis independently of changes in disease activity and levels of leptin and adiponectin: a randomised study over two years

## Study objectives

The purpose of this study was to evaluate if anti-tumour necrosis factor alpha (TNF) treatment in early rheumatoid arthritis (RA) had an impact on body composition and bone mineral density (BMD) beyond the anti-inflammatory effects and besides those that could be achieved by intensive disease-modifying anti-rheumatic drugs (DMARD) combination therapy with addition of sulfasalazine and hydroxychloroquine.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Karolinska University Hospital Ethics Committee approved on the 7th April 2004 (ref: 04-088/3)

## Study design

Open randomised controlled parallel study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet (Swedish only)

## Health condition(s) or problem(s) studied

Rheumatoid arthritis

## Interventions

After 3 months the patients who had not achieved low disease activity were randomised:

Treatment A: methotrexate with addition of sulphasalazine, 2000 mg/day, and hydroxychloroquine, 400 mg daily

Treatment B: methotrexate with the addition of the TNF antagonist infliximab, 3 mg/kg body weight given intravenously at weeks 0, 2, 6 and every 8 weeks thereafter

The total duration of treatment and follow-up in this study is two years.

**Intervention Type**

Drug

**Phase**

Phase IV

**Drug/device/biological/vaccine name(s)**

Methotrexate, sulphasalazine, hydroxychloroquine, infliximab

**Primary outcome measure**

Effects of anti-TNF treatment on body composition and BMD beyond the anti-inflammatory effect. Assessed by dual X-ray absorptiometry for total body, lumbar spine and femoral neck at the time of randomisation and after 12 and 24 months.

**Secondary outcome measures**

Changes in serum levels of the adipokines adiponectin and leptin determined by radio immunoassay at randomisation and after 12 and 24 months.

**Overall study start date**

29/03/2004

**Completion date**

13/12/2007

**Eligibility****Key inclusion criteria**

1. Patients with early RA (disease duration less than 12 months)
2. Participated in the Swefot (SWEdish PHarmacOTherapy) study at Karolinska University Hospital at Huddinge
3. Patients started treatment with methotrexate
4. Active disease defined as a Disease Activity Score of 28 joints (DAS28) above 3.2
5. Aged between 18 and 80 years, either sex

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

40 patients

**Key exclusion criteria**

1. Prior DMARD therapy
2. Contraindication to any of the trial medications

**Date of first enrolment**

29/03/2004

**Date of final enrolment**

13/12/2007

## Locations

**Countries of recruitment**

Sweden

**Study participating centre**

Department of Rheumatology, R92

Stockholm

Sweden

14186

## Sponsor information

**Organisation**

Karolinska University Hospital (Sweden)

**Sponsor details**

c/o Johan Bratt

Department of Rheumatology R92

Huddinge

Stockholm

Sweden

14186

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.karolinska.se/>

**ROR**

<https://ror.org/00m8d6786>

## Funder(s)

**Funder type**

Charity

**Funder Name**

The Swedish Rheumatism Association (Sweden)

**Funder Name**

King Gustav V 80 year's Foundation (Sweden)

**Funder Name**

Family Erling-Persson Foundation (Sweden)

**Funder Name**

Swedish Research Council (Sweden)

**Alternative Name(s)**

Swedish Research Council, VR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Sweden

**Funder Name**

The Regional Agreement on Medical Training and Clinical Research (ALF) between Stockholm County Council and the Karolinska Institutet (Sweden)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2010		Yes	No