

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

Submission date 26/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/04/2011	Condition category 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

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Additional identifiers

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

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?
Results article	results	01/11/2010		Yes	No