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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

Registration date
06/04/2010

Overall study status
Completed

Last Edited
06/04/2011

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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 absortiometry 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?
Results article	results	01/11/2010		Yes	No