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A randomised controlled trial evaluating the effects of hormone replacement therapy (HRT) on bone mineral density (BMD) and disease course in postmenopausal women with rheumatoid arthritis (RA)

Submission date
03/03/2004

Registration date
22/04/2004

Last Edited
30/06/2009

Recruitment status
No longer recruiting

Overall study status
Completed

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

Study objectives
Rheumatoid arthritis (RA) is a chronic disabling inflammatory rheumatic disease involving predominantly the joints and often also other organs such as the lungs and heart. The disease increases the risk of developing osteoporosis and fractures related to the reduced bone mineral density (BMD). The prevalence of the disease is 0.5 - 1% and women are more frequently affected.

The aims of the study were to assess the effects of HRT on:
1. The clinical disease activity
2. Laboratory measures of inflammation
3. BMD
4. Joint destruction by scoring radiographs
5. Biochemical markers of bone and cartilage metabolism
6. Pro-inflammatory cytokines and insulin like growth factor 1

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee at the Göteborg University.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Rheumatoid arthritis

Interventions
Eighty-eight women were randomised to:
1. HRT group (41 women): receive HRT and 500 mg calcium and 400 IU vitamin D3
2. Control group (47 women): receive 500 mg calcium and 400 IU vitamin D3 alone

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Hormone replacement therapy

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2004

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. Postmenopausal women with RA between 45 and 55 years old
2. Active disease, which met at least two of the following criteria:
2.1. At least six painful joints
2.2. At least three swollen joints
2.3. Erythrocyte sedimentation rate (ESR) at least 20 mm per hour
2.4. C-reactive protein (CRP) at least 10 mg/l
2.5. Fulfils the American Rheumatism Association 1987 revised criteria for adult RA
3. A maximum daily dose of 7.5 mg of prednisolone was accepted
4. Not receiving, or had not been using in the past two years, drugs affecting bone metabolism (HRT or bisphosphonates), except calcium and vitamin D3, which were allowed
5. No contra-indications to HRT

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
88

Key exclusion criteria
Does not comply with above inclusion criteria.

Date of first enrolment
01/04/2004

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Sweden

Study participating centre
Sahlgrenska Academy at Göteborg University
Göteborg
Sweden
S-413 46

Sponsor information

Organisation
Sahlgrenska Academy at Göteborg University (Sweden)

Sponsor details
The Department of Rheumatology and Inflammation Research
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Sponsor type
University/education

Website
http://www.sahlgrenska.gu.se/english/

ROR
https://ror.org/01tm6cn81

Funder(s)

Funder type
Research organisation

Funder Name
Regional Research Sources from Västra Götaland (Sweden)

Funder Name
Novo Nordisk Scandinavia AB Research Foundation (Sweden)

Funder Name
The Rune and Ulla Amlövs Foundation for Neurological and Rheumatological Research (Rune och Ulla Amlövs Stiftelse for Neurologisk och Reumatologisk Forskning) (Sweden)

Funder Name
The Research Foundation of Trygg-Hansa (Sweden)

Funder Name
The Swedish and Göteborg Association against Rheumatism (Sweden)

Funder Name
Reumaforskningsfond Margareta (Sweden)

Funder Name
King Gustav V's 80-years Foundation (Sweden)

Funder Name
The Medical Society of Göteborg (Sweden)

Funder Name

The Medical Faculty of Göteborg (LUA) (Sweden)

Funder Name
Nycomed (Sweden) - provided the calcium and vitamin D3 medication

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	01/04/2004		Yes	No
Results article	results	01/07/2009		Yes	No