ISRCTN95526224 https://doi.org/10.1186/ISRCTN95526224

In vivo longitudinal evaluation of vertebral bone strength in patients with rheumatoid arthritis treated with alendronate

Submission date 28/08/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 10/09/2007	**Overall study status** Completed	
Last Edited 10/06/2021	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Taro Mawatari

Contact details
3-1-1 Maidashi
Higashi-ku
Fukuoka
Japan
812-8582

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
In vivo longitudinal evaluation of vertebral bone strength in patients with rheumatoid arthritis treated with alendronate

Study objectives
To investigate the effect of alendronate in Rheumatoid Arthritis (RA) patients by non-invasive assessment of vertebral strength using finite element analysis of Quantitative Computed Tomography (QCT) scans.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Internal Committee of Kyushu University, composed of various departments of the University. Approved on 01/24/2000. (Please note that this ethics committee has been replaced by an established Institutional Review Board as of 07/09/2007).

Study design
Prospective randomized controlled trial, single center.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Treatment arm: 5 mg of oral alendronate once daily
Control arm: Standard care only

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

alendronate

Primary outcome measure
Longitudinal evaluation for the following was done at baseline and at least 7 months after the baseline assessment (average follow-up was 12.15 months), and percentage change was calculated:
1. BMD assessed by Dual energy X-ray Absorptiometry (DXA)
2. Various parameters (such as bone volume fraction, vertebral compressive strength), derived from quantitative CT evaluation including finite element analysis

Secondary outcome measures
RA disease activity was assessed by Disease Activity Score (DAS-28), at least 7 months after the baseline assessment (average follow-up was 12.15 months).

Overall study start date
01/09/2001

Completion date
21/08/2003

Eligibility

Key inclusion criteria
Female postmenopausal patients with RA who met the American College of Rheumatology diagnostic criteria for RA.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. The presence of abnormalities on spinal radiographs such as severe osteophytosis, scoliosis, spinal fusion, fracture deformation
2. Any disease known to affect bone turnover
3. Current or past glucocorticoid therapy comprising greater than 7.5 mg/day (predonisone equivalent)
4. Current or past use of anabolic steroids, calcitonin, supplemental vitamin D or vitamin K,

bisphosphonate
5. Current or past hormone replacement therapy
6. Spinal areal Bone Mineral Density (BMD) T-score greater than -1.0

Date of first enrolment
01/09/2001

Date of final enrolment
21/08/2003

Locations

Countries of recruitment
Japan

Study participating centre
3-1-1 Maidashi
Fukuoka
Japan
812-8582

Sponsor information

Organisation
Kyushu University, Department of Orthopaedic Surgery (Japan)

Sponsor details
Graduate School of Medical Sciences
3-1-1 Maidashi
Higashi-ku
Fukuoka
Japan
812-8582

Sponsor type
University/education

ROR
https://ror.org/00p4k0j84

Funder(s)

Funder type

Other

Funder Name
The Japanese Society of Clinical Pharmacology and Therapeutics

Funder Name
The Japanese Osteoporosis Foundation

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		01/11/2008	10/06/2021	Yes	No