

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	<input type="checkbox"/> Prospectively registered
Registration date 10/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/06/2021	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

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 (Please note that this ethics committee has been replaced by an established Institutional Review Board as of 07/09/2007).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 (prednisone 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