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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

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 (Please note that this ethics committee has been replaced by an established Institutional Review Board as of 07/09/2007).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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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).

Completion date

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

Sponsor information

Organisation

Kyushu University, Department of Orthopaedic Surgery (Japan)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results article01/11/200810/06/2021YesNo