

Osteogenesis and osteoclast inhibition in rheumatoid arthritis patients after more than 4 years of treatment with bisphosphonates or bisphosphonates with pitavastatin

Submission date 22/08/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/09/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/02/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims:

Rheumatoid arthritis is a long-term condition that causes joint pain, swelling and stiffness. Bisphosphonates are a group of drugs that work by slowing bone loss. Statins are another group of drugs that may affect bone mineral density (the amount of bone mineral in bone tissue) and bone metabolism (the breakdown of old bone tissue and formation of new bone tissue). The aim of this study is to assess the effects of bisphosphonates, alone and in combination with statins, on the bone mineral density and bone metabolism of rheumatoid arthritis patients.

Who can participate?

Patients aged over 40 with rheumatoid arthritis who have been treated with bisphosphonates but not statins

What does the study involve?

Participants are randomly allocated into two groups. Participants in one group are treated with bisphosphonates and participants in the other group are treated with bisphosphonates and statins.

The blood levels of markers of bone metabolism are measured, and bone mineral density at the radius (forearm), lumbar spine (lower back), and femoral neck (thigh bone) are measured using X-ray scans over an 18-month period of treatment.

What are the possible benefits and risks of participating?

Participants may benefit from knowing about their bone mineral density and bone metabolic markers. The possible risks are the side effects of statins (muscle disease, liver function disturbance and jaundice).

Where is the study run from?

Tokyo Metropolitan Bokutoh Hospital (Japan)

When is the study starting and how long is it expected to run for?

June 2009 to March 2011

Who is funding the study?

Tokyo Metropolitan Bokutoh Hospital (Japan)

Who is the main contact?

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Osteogenesis and osteoclast inhibition in rheumatoid arthritis patients after more than 4 years of treatment with bisphosphonates or bisphosphonates with pitavastatin over an 18 month follow up: a randomized controlled trial

Acronym

ORAB

Study objectives

Significant difference between bisphosphonates and combination with bisphosphonates + statin for bone mineral density and bone metabolic markers

Ethics approval required

Old ethics approval format

Ethics approval(s)

Tokyo Metropolitan Bokutoh Hospital, 27/03/2009

Study design

Randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Rheumatoid arthritis

Interventions

Bone metabolic markers (serum NTX, TRACP-5b, PICP and RANKL) were measured by ELISA. BMD of the radius, femoral neck, and lumbar spine were measured by DXA. The drugs administered in the Bis group were 35 mg of alendronate in 31 patients, 400 mg of etidronate in 4 patients, and 17.5 mg of risedronate in 7 patients. The drugs administered in the Bis+statin group were alendronate and 2 mg of pitavastatin in 26 patients, etidronate and pitavastatin in 5 patients, and risedronate and pitavastatin in 4 patients. A 400 mg dose of etidronate was administered orally between meals for 2 weeks, and was then withheld for the next 10 weeks. This 12-week period was defined as one cycle of etidronate treatment, and the cycle was repeated 6 times (72 weeks, 18 months).

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Alendronate, etidronate, risedronate, pitavastatin

Primary outcome(s)

Bone mineral densities of the radius, lumbar spine and femoral neck and bone mineral markers of NTX, TRAP-5b, PICP and RANKL at baseline, 6, 12 and 18 months

Key secondary outcome(s)

Percentage changes in all of the parameters (bone mineral densities of the radius, lumbar spine and femoral neck, bone mineral markers of NTX, TRAP-5b, PICP and RANKL) at 0, 6, 12, 18 months

Completion date

31/03/2011

Eligibility

Key inclusion criteria

1. Aged over 40 years old
2. Pre-menopausal patients with rheumatoid arthritis, and not planning pregnancy
3. Postmenopausal patients
4. Patients receiving bisphosphonates
5. Patients receiving bisphosphonates and not receiving statins who diagnosed hyperlipidemia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Adverse or allergic reactions to statins
2. Severe liver function disturbance
3. Severe renal function disturbance
4. Patients with rheumatoid arthritis during pregnancy or during nursing
5. Patients with probability of pregnancy
6. Patients receiving statins
7. Patients with other severe complications

Date of first enrolment

01/06/2009

Date of final enrolment

31/03/2011

Locations**Countries of recruitment**

Japan

Study participating centre

Tokyo Metropolitan Bokutoh Hospital

Tokyo

Japan

130-8575

Sponsor information

Organisation

Tokyo Metropolitan Bokutoh Hospital (Japan)

ROR

<https://ror.org/01dk3f134>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Tokyo Metropolitan Bokutoh Hospital (Japan)

Results and Publications**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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes