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	 Prospectively registered Protocol
Registration date 04/09/2012	Overall study status Completed	 Statistical analysis plan Results
Last Edited 06/02/2017	Condition category Musculoskeletal Diseases	Individual participant dataRecord 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? Dr Masakazu Nagashima m_nagashima@bokutoh-hp.metro.tokyo.jp

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

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

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/06/2009

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 diagnozed hyperlipidemia

Participant type(s)

Patient

Age group

Adult

Sex Both

Target number of participants

77 male and female

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 nuring
- 5. Patients with probability of pregnancy
- 6. Patients receiving statins
- 7. Patients with other sever 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)

Sponsor details c/o Dr Masakazu Nagashima 4-23-15 Kohtohbashi Sumida-ku Tokyo Japan 130-8575 +81 (0)3 3633 6151 m_nagashima@bokutoh-hp.metro.tokyo.jp

Sponsor type Hospital/treatment centre

ROR https://ror.org/01dk3f134

Funder(s)

Funder type Hospital/treatment centre

Funder Name Tokyo Metropolitan Bokutoh Hospital (Japan)

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