ISRCTN45993953 https://doi.org/10.1186/ISRCTN45993953

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

Registration date
04/09/2012

Overall study status
Completed

Last Edited
06/02/2017

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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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
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Sponsor information

Organisation
Tokyo Metropolitan Bokutoh Hospital (Japan)

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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