

Randomised, open-label, multi-centre study designed to reflect routine clinical care in order to assess persistence on treatment in women with postmenopausal osteoporosis receiving once-monthly ibandronate with a patient support programme versus once-weekly alendronate

Submission date 25/07/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 25/08/2005	Overall study status Completed	☐ Protocol
Last Edited 16/09/2009	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

Study information

Scientific Title

Acronym

PERSIST

Study objectives

Monthly ibandronate with a patient support programme increases persistence on treatment compared to weekly alendronate. This will be tested using survival analysis techniques.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multicentre randomised open label active controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Postmenopausal Osteoporosis

Interventions

The once-monthly single tablet of ibandronate 150 mg (study drug) will be provided for those patients randomised to group A together with a patient support programme, and the comparator alendronate 70 mg weekly will be provided for those patients randomised to group B

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ibandronate, alendronate

Primary outcome(s)

Persistence (time on therapy) of patients receiving once-monthly dosing of ibandronate with patient support programme versus patients receiving once-weekly alendronate. Persistence

with therapy will be measured on the basis of the number of months of study drug dispensed to the patient by the pharmacy i.e. prescription refills.

Key secondary outcome(s))

1. All patients that withdraw from the study must have the reason for discontinuation recorded
2. All adverse events will be reported as part of general safety assessments

Completion date

30/06/2005

Eligibility

Key inclusion criteria

1. Women with postmenopausal osteoporosis diagnosed according to clinical judgement of the treating physician
2. Patients who, in the opinion of the investigator, are able to comply with the protocol requirements and are independent (self-caring)
3. Patients who have signed informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Patients who were previously exposed to or are currently on a biphosphonate
2. Unlikely to complete the entire 6-month study period due to significant medical condition
3. Inability to stand or sit upright for at least 60 minutes
4. Abnormalities of the oesophagus that delay oesophageal emptying, such as achalasia and stricture
5. Hypersensitivity to biphosphonates
6. Administration of any investigational drug within 30 days preceeding the first dose of study drug

Date of first enrolment

01/12/2004

Date of final enrolment

30/06/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Bridge House Medical Centre
Crawley
United Kingdom
RH10 1LL

Sponsor information

Organisation
Roche Products Limited (UK)

ROR
<https://ror.org/024tgbv41>

Funder(s)

Funder type
Industry

Funder Name
Roche Products Limited (UK)

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?
Results article	results	01/08/2006		Yes	No