ISRCTN79315974 https://doi.org/10.1186/ISRCTN79315974

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

Registration date
25/08/2005

Overall study status
Completed

Last Edited
16/09/2009

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MA18160

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/12/2004

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

Age group
Adult

Sex
Female

Target number of participants
1000

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
England

United Kingdom

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

Sponsor information

Organisation
Roche Products Limited (UK)

Sponsor details
40 Broadwater Road
Welwyn Garden City
United Kingdom
AL7 3AY

Sponsor type
Industry

ROR
https://ror.org/024tgbv41

Funder(s)

Funder type
Industry

Funder Name
Roche Products Limited (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2006		Yes	No