ISRCTN64773345 https://doi.org/10.1186/ISRCTN64773345

Open-label, multicentre study to assess the persistence on treatment in women with postmenopausal osteoporosis receiving once-monthly ibandronic acid with either a patient support programme (PSP) or bone turnover marker monitoring (BM)

Submission date
13/06/2005

Recruitment status
No longer recruiting

Registration date
15/08/2005

Overall study status
Completed

Last Edited
31/07/2012

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
ML 18373

Study information

Scientific Title

Acronym
Back up study

Study objectives
The aim of the study is to compare the persistence rates of patients treated with once-monthly ibandronic acid who receive feedback on the change in their bone turnover marker with patients who receive once-monthly ibandronic acid and a patient support programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multicentre randomised open label controlled trial

Primary study design
Interventional

Secondary study design
Multi-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Osteoporosis

Interventions
Patients randomised to:
1. Treatment with once-monthly ibandronic acid and feedback on the change in their bone turnover marker
2. Treatment with once-monthly ibandronic acid and a patient support programme

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
To assess persistence on treatment (time on therapy) of once-monthly ibandronic acid when patients are randomised to either ibandronic acid with patient support programme (PSP) or once-monthly ibandronic acid with bone turnover marker monitoring (BM).

Secondary outcome measures
To ascertain reasons for discontinuation from treatment.

Overall study start date
06/06/2005

Completion date
28/02/2006

Eligibility

Key inclusion criteria
1. Women with postmenopausal osteoporosis diagnosed according to the clinical judgment 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
Senior

Sex
Female

Target number of participants
600

Key exclusion criteria
1. Patients who were previously exposed to or are currently on a bisphosphonate
2. Patients who have had a fracture(s) in the past 6 months
3. Patients who have been on hormone replacement therapy (HRT) in the past 6 months
4. Patients who are unlikely to complete the entire 6-month study period due to significant medical condition
5. Patients with an inability to stand or sit upright for at least 60 minutes
6. Patients with abnormalities of the oesophagus that delay oesophageal emptying, such as achalasia and stricture

7. Patients with hypersensitivity to bisphosphonates
8. Administration of any investigational drug within 30 days preceding the first dose of the study drug
9. Patients with galactose intolerance

Date of first enrolment
06/06/2005

Date of final enrolment
28/02/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Roche Products Ltd
Welwyn Garden City
United Kingdom
AL7 3AY

Sponsor information

Organisation
Roche Products Ltd (UK)

Sponsor details
Hexagon Place
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Sponsor type
Industry

Website
http://www.roche.com

ROR
https://ror.org/024tgbv41

Funder(s)

Funder type
Industry

Funder Name
Roche Products Ltd (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