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Radiotherapy with or without ibandronate in the treatment of painful bone metastases of prostate cancer

Submission date	Recruitment status	[ ] Prospectively registered
09/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/01/2006	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
03/04/2006	Cancer	[ ] 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

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
The purpose of this study is to evaluate the efficacy of oral ibandronate (versus placebo) added to the standard radiotherapy regimen for painful bone metastases to reduce pain, to reduce the need of analgesics, and to reduce skeletal-related events (impending fractures, need of repeated radiotherapy, or surgery).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Prostate Cancer

Interventions
Ibandronate tablet or placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
ibandronate

Primary outcome(s)
Primary objective will be pain reduction on the pain scale (scale 0-10) at 12 weeks of treatment. Response of treatment will be defined as a reduction of at least two points of the pain scale.

Key secondary outcome(s))
1. Pain reduction on the pain scale at 4-8-16-20-24 weeks of treatment. Use of analgesics at 4-8-12-16-20-24 weeks of treatment.
2. New skeletal-related events (= time to progression, including fractures, need of repeated radiotherapy, surgery)
3. Side effects at 4-8-12-16-20-24 weeks of treatment
4. Quality of Life, as measured by the EORTC-QLQ-C30 and EQ-5D, at 12-24 weeks

Completion date

01/12/2007

Eligibility

Key inclusion criteria
1. Karnofsky score >60%
2. Written informed consent
3. Histologically proven PC with documented (bone scintigraphy, CT scan, MRI, or conventional X-Ray) bone metastases, without spinal cord/cauda equina compression
4. Indication for analgesic radiotherapy
5. Estimated life expectancy of >6 months
6. Clinically documented painful bone metastases
7. Indication for analgesic radiotherapy for the painful bone metastases

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Previous treatment with any kind of bisphosphonates or radionuclides
2. Hypercalcemia (serum calcium level >2.65 mmol/l), hypocalcemia (serum calcium level <2.2 mmol/l), impaired renal function (creatinine >266 µmol/l; albumin >50 g/l), according to the medical charts
3. Investigational drugs within 30 days before study entry
4. Paget's disease
5. Untreated esophagitis or gastric ulcer

Date of first enrolment
01/12/2005

Date of final enrolment
01/12/2007

Locations

Countries of recruitment
Netherlands

Study participating centre

Erasmus Medical Center
Rotterdam
Netherlands
3008 AE

Sponsor information

Organisation
Erasmus Medical Center (The Netherlands)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Industry

Funder Name
Roche Nederland BV

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration