

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

Submission date 09/01/2006	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 09/01/2006	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 03/04/2006	Condition category Cancer	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr L. Incrocci

Contact details
Erasmus Medical Center
Daniel den Hoed Cancer Center
P.O. Box 5201
Rotterdam
Netherlands
3008 AE
+31 (0)10 4391421
l.incrocci@erasmusmc.nl

Additional identifiers

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

Primary study design

Interventional

Study design

Randomised controlled trial

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