ISRCTN86185157 https://doi.org/10.1186/ISRCTN86185157

A multicentre randomised trial of single dose Radiotherapy compared to Ibandronate for localised metastatic Bone pain

Submission date 02/06/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/06/2003	**Overall study status** Completed	
Last Edited 28/10/2021	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-radiotherapy-or-ibandronate-for-pain-caused-by-prostate-cancer-that-has-spread-to-the-bone

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00082927

Protocol serial number
C2422/A3027

Study information

Scientific Title
A multicentre randomised trial of single dose Radiotherapy compared to Ibandronate for localised metastatic Bone pain

Acronym
RIB

Study objectives
The current standard treatment for localised metastatic bone pain in the United Kingdom is single dose RadioTherapy (RT). There is also increasing evidence for, and use of, the bisphosphonate class of drugs in this setting. Their activity in bone pain from primary tumours of breast, lung and prostate has been shown in both single arm phase II studies and randomised double blind placebo controlled trials. No direct comparison between any bisphosphonate and RT has been undertaken.

The objective of this trial is to determine whether ibandronate given as a single intravenous infusion of 6 mg can give comparable rates of pain control as a single 8 Gy dose of local RT. 580 eligible patients with localised metastatic bone pain will be randomised to receive either treatment. Patients failing to achieve pain response at four weeks after initial treatment will be offered the alternate treatment arm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Localised metastatic bone pain

Interventions
There are two trial groups:
Group 1 will be given a single dose of radiotherapy.
Group 2 will be given a single dose of Ibandronate intravenously over one to two hours.

There will be systematic patient reported measurements of pain (which will be measured using a patient-completed pain assessment questionnaire based on the Wisconsin Brief Pain Inventory

and adapted by the Radiation Therapy Oncology Group [RTOG] for bone pain), and quality of life (which will be measured using the Functional Assessment of Chronic Illness Therapy [FACIT] scale).

Intervention Type
Drug

Phase
Phase III

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

Primary outcome(s)
Pain response at 4 and 12 weeks post treatment. Formal definition of response includes pain score and analgesic use to achieve complete or partial response.

Key secondary outcome(s))
Quality of life and bone morbidity events including retreatment for bone pain, pathological fracture and spinal cord compression.

In addition, osteoclast activity will be measured using the urinary markers pyridinoline and deoxypyridinoline, and the relation of changing levels after treatment with response will be explored.

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Histologically or cytologically proven underlying primary malignancy of breast, lung or prostate, or sclerotic bone metastases in a patient presenting with a serum Prostate Specific Antigen (PSA) more than 100ng/ml
2. Bone metastases confirmed radiologically on plain x-ray, isotope scan, Computed Tomography (CT) or Magnetic Resonance (MR) scan
3. Single localised metastatic bone pain receiving optimal analgesics and adjuvant drugs including Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) unless contraindicated.
4. Clinical diagnosis of metastatic bone pain for which radiotherapy is indicated
5. Aged over 18 yrs with no upper age limit
6. Able to comply with pain chart and quality of life assessments
7. Able to give written informed consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Predicted life expectancy less than three months
2. Bisphosphonate treatment within the last six months
3. Any previous treatment that contraindicated radiotherapy or ibandronate or that would interfere with the action of either
4. Unfit to receive radiotherapy and ibandronate
5. Aspirin sensitive asthma in past medical history
6. Pregnancy and lactation

Date of first enrolment
01/04/2003

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Mount Vernon Hospital
Northwood
United Kingdom
HA6 2RN

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Industry

Funder Name
Cancer Research UK (CRUK((UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Funder Name
Roche (UK) - have committed to providing free ibandronate

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/08/2015		Yes	No