

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

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<b>Registration date</b> 02/06/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/10/2021	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## 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

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number  
NCT00082927

## Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

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.

**Secondary outcome measures**

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.

**Overall study start date**

01/04/2003

**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

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Both

### **Target number of participants**

580

### **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**

England

United Kingdom

### **Study participating centre**

**Mount Vernon Hospital**

Northwood

United Kingdom

HA6 2RN

# Sponsor information

## Organisation

Cancer Research UK (CRUK) (UK)

## Sponsor details

P.O. Box 123  
Lincoln's Inn Fields  
London  
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## Sponsor type

Charity

## Website

<http://www.cancerresearch.org.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, 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

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	04/08/2015		Yes	No