

# A double-blind placebo-controlled randomised trial of oral sodium clodronate for metastatic prostate adenocarcinoma

<b>Submission date</b> 06/04/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/04/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/04/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

[http://www.ctu.mrc.ac.uk/research\\_areas/study\\_details.aspx?s=60](http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=60)

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PR05

# Study information

## Scientific Title

### Study objectives

Measure the efficacy and safety of oral sodium clodronate in preventing symptomatic bone disease

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Double blind placebo-controlled randomised trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Prevention

## Participant information sheet

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

Prostate cancer

### Interventions

1. One group receives 3 years of oral sodium clodronate
2. The other group receives a matching placebo for 3 years

### Intervention Type

Drug

### Phase

Not Specified

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

Oral sodium clodronate

### Primary outcome measure

Time to symptomatic bone progression; overall survival; impact on analgesic consumption.

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/06/1994

### **Completion date**

01/07/1998

## **Eligibility**

### **Key inclusion criteria**

1. Proven histological diagnosis of prostate cancer or Prostate-Specific Antigen (PSA) more than 100 mg/l
2. Metastatic bone disease demonstrated on bone scan or skeletal radiographs (Stage M1b)
3. Patients commencing or clinically responding to initial hormone treatment with orchidectomy, Luteinising Hormone Releasing Hormone (LHRH) analogues, cyproterone acetate, flutamide or complete androgen blockade but with no previous hormone treatment
4. Normocalcaemic (serum calcium within the normal range of the centre)
5. WHO performance status of 0, 1 or 2
6. No concomitant or previous use of other bisphosphonates
7. Serum creatinine less than twice upper limit of normal range of centre
8. No administration of any investigational drug within 12 months

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Male

### **Target number of participants**

311

### **Key exclusion criteria**

Does not meet inclusion criteria

### **Date of first enrolment**

01/06/1994

### **Date of final enrolment**

01/07/1998

## **Locations**

### **Countries of recruitment**

England

United Kingdom

**Study participating centre**

**MRC Clinical Trials Unit**

London

United Kingdom

NW1 2DA

## **Sponsor information**

**Organisation**

Medical Research Council (MRC) (UK)

**Sponsor details**

20 Park Crescent

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clinical.trial@headoffice.mrc.ac.uk

**Sponsor type**

Research council

**Website**

<http://www.mrc.ac.uk>

## **Funder(s)**

**Funder type**

Research council

**Funder Name**

Medical Research Council (MRC) (UK)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

Boehringer Mannheim / Roche (Switzerland)

## 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	03/09/2003		Yes	No
<a href="#">Results article</a>	results	01/09/2009		Yes	No