

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

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

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

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**

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (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**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?
Results article	results	03/09/2003		Yes	No
Results article	results	01/09/2009		Yes	No