ISRCTN38477744 https://doi.org/10.1186/ISRCTN38477744

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2000	**Overall study status** Completed	
Last Edited 12/04/2012	**Condition category** Cancer	

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=60

Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Double blind placebo-controlled randomised trial

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, Medical Research Committee and Advisory 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