ISRCTN83688026 https://doi.org/10.1186/ISRCTN83688026

A randomised controlled clinical trial to evaluate the anti-osteolytic agent clodronate for the prevention of the development of bone metastases in patients with primary breast cancer

Submission date 01/02/2006	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 01/02/2006	Overall study status Completed	 Statistical analysis plan [X] Results
Last Edited 22/08/2012	Condition category Cancer	[_] Individual participant data

Plain English summary of protocol Not provided at time of registration

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Study objectives

That the use of the anti-osteolytic bisphosphonate clodronate will prevent the development of bone metastases in patients with primary operable breast cancer

Ethics approval required Old ethics approval format

Ethics approval(s) Royal Marsden Hospital Research Ethics Committee, protocol number 444, approval received 1988

Study design Randomised, double-blind, placebo-controlled, multicentre, phase III trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) Not specified

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 Breast cancer

Interventions Clodronate 1600 mg taken orally per day for two years

Intervention Type Drug

Phase Phase III Drug/device/biological/vaccine name(s)

Bisphosphonate clodronate

Primary outcome measure Time to first bone metastases over five-year study period

Secondary outcome measures Survival

Overall study start date 01/01/1989

Completion date 01/01/1995

Eligibility

Key inclusion criteria

Histologically or cytologically confirmed primary operable breast cancer with no evidence of metastases

Participant type(s) Patient

Age group Adult

Sex Female

Target number of participants 1000

Key exclusion criteria

- 1. Significant renal, hepatic or non-malignant bone disease
- 2. Previous history of malignant disease
- 3. Prior bisphosphonate use

Date of first enrolment 01/01/1989

Date of final enrolment 01/01/1995

Locations

Countries of recruitment England **Study participating centre Parkside Oncology Clinic** London United Kingdom SW19 4NB

Sponsor information

Organisation Royal Marsden Hospital (UK), secondary sponsor Schering (Germany)

Sponsor details Downs Road Sutton England United Kingdom SM2 5PT

Sponsor type Hospital/treatment centre

Website http://www.royalmarsden.org

ROR https://ror.org/034vb5t35

Funder(s)

Funder type Other

Funder Name Royal Marsden hospital research fund (UK)

Funder Name Leiras Oy (Finland)

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?
Results article	results	01/03/2006		Yes	Νο