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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/02/2006	**Overall study status** Completed	
Last Edited 22/08/2012	**Condition category** Cancer	

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

United Kingdom

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	No