

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 01/02/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 22/08/2012	Condition category Cancer	<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

Time to first bone metastases over five-year study period

Key secondary outcome(s)

Survival

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Parkside Oncology Clinic

London

United Kingdom

SW19 4NB

Sponsor information

Organisation

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

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

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