ISRCTN29188871 https://doi.org/10.1186/ISRCTN29188871

A phase II, double blind, randomised, dose ranging, safety and efficacy trial of rapid intravenous infusion of Zoledronate versus Aredia in breast cancer patients with osteolytic metastases

Submission date	Recruitment status	[ ] Prospectively registered
19/08/2002	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/08/2002	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/12/2019	Cancer	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
C120

Study information

Scientific Title
A phase II, double blind, randomised, dose ranging, safety and efficacy trial of rapid intravenous infusion of Zoledronate versus Aredia in breast cancer patients with osteolytic metastases

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Breast cancer

Interventions
All patients receive treatment for 9 months.

Patients are randomised to one of four treatment groups:
1. Group A: Zoledronate 0.4 mg in 50 ml normal saline rapid infusion every 4 weeks followed by 250 ml 0.9% normal saline 2 h infusion every 4 weeks.
2. Group B: Zoledronate 2 mg in 50 ml normal saline rapid infusion every 4 weeks followed by 250 ml 0.9% normal saline 2 h infusion every 4 weeks.
3. Group C: Zoledronate 4 mg in 50 ml normal saline rapid infusion every 4 weeks followed by 250 ml 0.9% normal saline 2 h infusion every 4 weeks.
4. Group D: Normal saline, 50 ml rapid infusion every 4 weeks followed by 90 mg Aredia (pamidronate) in 250 ml normal saline 2 h infusion every 4 weeks.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Zoledronate, Aredia

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1995

Completion date
31/01/1998

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Histologically confirmed diagnosis of breast cancer
3. At least one osteolytic lesion which measures at least 1 cm in diameter which has not been treated with radiation therapy in the 3 months prior to the start of treatment
4. Metastatic bone lesions confirmed by plain films
5. Life expectancy of at least 10 months
6. Performance status (Eastern Cooperative Oncology Group [ECOG]) of 1-2
7. Satisfactory haematological and blood chemistry values
8. No previous continuous treatment (> four doses) with a bisphosphate, or treatment with a bisphosphate within 3 months of the start of treatment. Treatment with another bisphosphate is not allowed at any time during the trial.
9. Patients for whom orthopaedic surgery to bone or radiation therapy to bone is currently scheduled to treat skeletal disease related to metastatic bone lesions may not enter the trial. A previous history of such procedures is permitted only if the procedure was completed more than 2 weeks prior to the start of treatment
10. Patients who develop hypercalcaemia may be treated with a standard therapy other than a bisphosphate and remain on the trial
11. No recent treatment with cacitonin, mitharmycin or gallium nitrate
12. No previous history of allergic reactions or sensitivity to bisphosphates
13. Normal electrocardiogram (ECG)

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1995

Date of final enrolment
31/01/1998

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
United Kingdom

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kate.law@cancer.org.uk

Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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