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A randomised phase II study of a loading dose of ibandronate schedules in patients with bone metastases from breast cancer

Submission date 31/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/09/2005	**Overall study status** Completed	
Last Edited 19/11/2015	**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

Protocol serial number
B91

Study information

Scientific Title
A randomised phase II study of a loading dose of ibandronate schedules in patients with bone metastases from breast cancer

Acronym
LDIS

Study objectives
To investigate if a loading dose can improve efficacy and time to biochemical response compared to standard oral therapy

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer patients with metastatic bone disease

Interventions
1. Intravenous ibandronate 12 mg day, followed on day 2 by oral ibandronate 50 mg po daily
2. Standard oral therapy of 50 mg daily from day 1

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Ibandronate

Primary outcome(s)
The primary study end-point is the percentage reduction in S-CTX-1 from baseline by day 5 on study

Key secondary outcome(s))
The secondary study end-point is the percentage reduction in S-CTX-1 level from baseline at the end of weeks 1-8 averaged

Completion date
01/01/2007

Eligibility

Key inclusion criteria
1. Female patient aged>=18 years. Indication for the treatment of metastatic bone disease with bisphosphonates
2. ECOG performance status 0, 1 or 2. Histologically confirmed diagnosis of breast cancer
3. Radiological evidence of metastatic bone disease
4. Life expectancy of greater than 6 months
5. Normal renal function
6. Liver function tests within 2 times the upper limit of normal for the local laboratory
7. Calcium levels within normal range for local laboratory (no evidence of hypercalcaemia or hypocalcaemia)
8. Patient is not pregnant or lactating and is willing to use adequate contraception
9. Written informed consent in accordance with local requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Bisphosphonate use within 6 months
2. Previous bisphosphonate hypersensitivity
3. Change in systemic anti-cancer treatment within 3 months preceeding trial entry
4. Administration of Strontium or Sumarium within 6 months of trial entry
5. Local radiotherapy within 2 weeks of study
6. Any other bone disease: Paget's disease of bone, metabolic bone disease
7. Psychiatric condition that would preclude obtaining informed consent
8. Bone active treatment within 3 months (i.e. HRT use) but Tamoxifen permitted
9. Concurrent vitamin D or retinoids
10. Active peptic ulcer
11. Acetylsalicylic acid sensitive asthma
12. Treatment with aminoglycosides

Date of first enrolment
11/06/2004

Date of final enrolment
01/01/2007

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Beatson Oncology Centre
Glasgow
United Kingdom
G11 6NT

Sponsor information

Organisation
Greater Glasgow NHS Board, North Glasgow Division (UK)

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Industry

Funder Name
Roche (UK)

Alternative Name(s)
F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co., Roche Holdings, Inc.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2015		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes