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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

Study website
http://www.crukctuglasgow.org/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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 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 measure
The primary study end-point is the percentage reduction in S-CTX-1 from baseline by day 5 on study

Secondary outcome measures
The secondary study end-point is the percentage reduction in S-CTX-1 level from baseline at the end of weeks 1-8 averaged

Overall study start date
11/06/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
44

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
Scotland

United Kingdom

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

Sponsor information

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

Sponsor details
West Research Office
Administration Building
Western Infirmary
Glasgow

Scotland
United Kingdom
G11 6NT

Sponsor type
Hospital/treatment centre

Website
http://www.ngt.org.uk/research/home.htm

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.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

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	01/04/2015		Yes	No