

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/11/2015	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.crukctuglasgow.org/>

Contact information

Type(s)

Scientific

Contact name

Dr Diana Ritchie

Contact details

Beatson Oncology Centre
Western Infirmary
Glasgow
United Kingdom
G11 6NT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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