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A randomised pragmatic open-label, multicentre, non-crossover clinical study to evaluate and compare the efficacy, safety profile and tolerability of oral ibandronate versus intravenous (iv) zoledronate in the treatment of breast cancer patients with bone metastases

Submission date 10/03/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 13/04/2005	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 26/10/2018	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-zoledronate-or-ibandronate-for-breast-cancer-that-has-spread-to-the-bones

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

2005-001710-40

ClinicalTrials.gov (NCT)
NCT00326820

Protocol serial number
N/A

Study information

Scientific Title
A randomised pragmatic open-label, multicentre, non-crossover clinical study to evaluate and compare the efficacy, safety profile and tolerability of oral ibandronate versus intravenous (iv) zoledronate in the treatment of breast cancer patients with bone metastases

Acronym
ZICE (Zoledronate vs Ibandronate Comparative Evaluation)

Study objectives
To demonstrate non-inferiority of oral ibandronate 50 mg daily in comparison with 34 weekly zoledronate 4 mg iv infusions and investigate the tolerability and side-effect profile of the two study arms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC for Wales on 19/08/2005. (MREC ref: 05/MRE09/57)

Study design
randomised pragmatic open-label, multicentre, non-crossover clinical study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast cancer with bone metastases

Interventions
Comparison of skeletal related events in patients on iv zoledronate given 3-4 weekly and oral daily ibandronate.
Blood samples analysed 3-4 weekly; lumbar and thoracic plain spine X-rays at baseline and end of treatment. Analysis of quality of life (QoL), analgesic usage and pain scoring.

Intervention Type
Drug

Phase
Phase III

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

Primary outcome(s)
Mean number of skeletal related events (SREs) per patient

Key secondary outcome(s))
Time to first SRE; Andersen-Gill Multiple-event analysis; Percentage of patients with any SRE; Pain/analgesic scores; Safety (including survival); Quality of Life (QoL); Cost efficiency analysis.

Completion date
30/09/2008

Eligibility

Key inclusion criteria
1. Patients with newly diagnosed (<3 months) multiple bone metastases from histologically proven breast cancer and considered suitable for treatment with a bisphosphonate
2. Isotope bone scan within 6 weeks prior to screening to provide evidence of multiple bone metastases
3. Patients may also be receiving chemotherapy and/or hormone therapy for metastatic disease
4. Patients with multiple (>1) bone metastases (painful or asymptomatic) of lytic, mixed or purely sclerotic type
5. Eastern Cooperative Oncology Group (ECOG) Performance Status 0, 1 or 2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Patients with a creatinine clearance of less than 30 ml/minute
2. Patients with serum bilirubin/aspartate transaminase (AST) (alanine transaminase [ALT]) raised more than 1.5 times normal
3. Patients with central nervous system (CNS) metastases
4. Patients who have undergone dental procedures in the 2 months prior to randomisation
5. Patients with known active peptic ulcer
6. Patients with hypocalcaemia within 6 weeks of randomisation
7. Patients who have received bisphosphonate therapy in the previous 6 months

Date of first enrolment
01/09/2005

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Velindre NHS Trust
Cardiff
United Kingdom
CF14 2TL

Sponsor information

Organisation
Velindre NHS Trust

ROR
https://ror.org/05ntqkc30

Funder(s)

Funder type
Industry

Funder Name
Roche Pharmaceuticals UK

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	sub-study results	09/10/2013		Yes	No
Plain English results				No	Yes