Zoledronate on bone mineral density in patients with cancer remission and antineoplastic treatment induced bone loss

Submission date 30/06/2010	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 30/06/2010	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 09/09/2015	Condition category Cancer	[_] Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Effect of an annual infusion of zoledronate on bone mineral density in patients on long term follow up with cancer remission and anti-neoplastic treatment induced bone loss study

Acronym

Annual zoledronate

Study objectives

No previous study has been carried out in men and women in long term remission from cancers such as breast cancer, lymphoma and testicular cancer with treatment induced osteopenia or osteoporosis. The aim of the proposed study was to determine whether in such patients, an annual 4 mg dose of intraveous (IV) zoledronic acid results in significant increase in bone mineral density (BMD) measured one year later. Further more to assess whether any benefit obtained in such patients is maintained.

Ethics approval required Old ethics approval format

Ethics approval(s) South Sheffield LREC approved on the 3rd September 2001 (ref: SSLREC/01/113)

Study design Multicentre non-randomised interventional treatment trial

Primary study design Interventional

Secondary study design Non randomised controlled trial

Study setting(s) GP practice

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

Topic: National Cancer Research Network; Subtopic: All Cancers/Misc Sites; Disease: Breast, Colon, Lymphoma (Hodgkin's), Lymphoma (non-Hodgkin's), Testis, Melanoma

Interventions

Zoledronic acid 4 mg intravenously once a year. DEXA scans at baseline, 1, and 2 years of lumbar spine and hip

Study entry: other

Intervention Type Drug

Phase Not Applicable

Drug/device/biological/vaccine name(s)

Zoledronic acid

Primary outcome measure

Change in BMD at hip and spine, measured by DEXA scan at 1 and 2 years

Secondary outcome measures

Improvement in bone resorption marker levels, measured at 0, 6, 12, 18, 24, 36, 48 and 60 months.

Overall study start date 01/09/2001

Completion date 01/10/2005

Eligibility

Key inclusion criteria

1. Histologically proven malignant disease

2. Complete response of primary disease to chemotherapy and/or radiotherapy and no evidence of metastases

3. Osteoporosis or osteopaenia (as defined by World Health Organization [WHO] criteria) at screening dual energy x-ray absorptiometry (DEXA) scan

4. Confirmation of post-menopausal status (female patients) as determined by serum folliclestimulating hormone (FSH) greater than 15 mU/ml and oestradiol levels of less than 30 pg/ml

5. Aged 18 years or above

6. Eastern cooperative oncology group (ECOG) performance status 0, 1 or 2

7. No previous treatment with bisphosphonate

8. No treatment with anabolic steroids, fluoride, calcitonin or vitamin D within the last six months 9. No change in endocrine therapy in last three months

10. Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule

11. Written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants Planned sample size: 80

Key exclusion criteria

1. Abnormal renal function (serum creatinine level greater than 130 $\mu\text{M/L}$ or greater than 1.5 mg /dL)

Pregnancy/lactation (female patients)
 Other disorders of bone metabolism e.g., Paget's disease, hyperparathyroidism, renal osteodystrophy

Date of first enrolment 01/09/2001

Date of final enrolment 01/10/2005

Locations

Countries of recruitment England

United Kingdom

Study participating centre Department of Clinical Oncology Sheffield United Kingdom S10 2SJ

Sponsor information

Organisation University of Sheffield (UK)

Sponsor details Royal Hallamshire Hospital Glossop Road Sheffield England United Kingdom S10 2JF +44 114 22 21448 R.J.Hudson@sheffield.ac.uk

Sponsor type University/education

Website http://www.sheffield.ac.uk/

ROR https://ror.org/05krs5044

Funder(s)

Funder type Charity

Funder Name Weston Park Cancer Appeal (UK)

Results and Publications

Publication and dissemination plan A follow up long term follow-up publication is planned for late 2015/early 2016.

Intention to publish date 01/02/2016

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?
<u>Results article</u>	Results :	15/09/2007		Yes	No