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Zoledronate on bone mineral density in patients with cancer remission and anti-neoplastic treatment induced bone loss

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

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 follicle-stimulating 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 µM/L or greater than 1.5 mg /dL)
2. Pregnancy/lactation (female patients)
3. 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
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Sponsor information

Organisation
University of Sheffield (UK)

Sponsor details
Royal Hallamshire Hospital
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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?
Results article	Results :	15/09/2007		Yes	No