

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 09/09/2015	Condition category Cancer	<input type="checkbox"/> 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

Protocol serial number
1195

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 intravenous (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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Abnormal renal function (serum creatinine level greater than 130 μ M/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

United Kingdom

England

Study participating centre

Department of Clinical Oncology

Sheffield

United Kingdom

S10 2SJ

Sponsor information

Organisation

University of Sheffield (UK)

ROR

<https://ror.org/05krs5044>

Funder(s)

Funder type

Charity

Funder Name

Weston Park Cancer Appeal (UK)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type

[Results article](#)

Details

Results :

Date created

15/09/2007

Date added

Peer reviewed?

Yes

Patient-facing?

No