

Zoledronate to prevent bone loss in acute multiple sclerosis

Submission date 08/04/2009	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 05/05/2009	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/08/2014	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Jonathan Tobias

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CZOL446HGB15T

Study information

Scientific Title

A randomised controlled trial to evaluate whether zoledronate prevents bone loss in acute multiple sclerosis

Study objectives

That a single dose of intravenous zoledronate 5 mg immediately prior to intravenous corticosteroid therapy will prevent the bone thinning effect of the steroid, therefore reducing the risk of a fracture.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South West Research Ethics Committee, 13/02/2009, ref: 08/H0206/76

Study design

Single-blind randomised two-arm placebo-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

Multiple sclerosis

Interventions

A single dose of intravenous zoledronate 5 mg/placebo prior to commencement of intravenous corticosteroid for acute exacerbation of multiple sclerosis symptoms. Blood samples taken on days 1, 2, 3, 7, 90, 180 and 360. Dual energy X-ray absorptiometry (DXA) scans taken on day 7, 90, 180 and 360.

Updated 11/08/2014: this trial was halted prematurely due to problems with recruitment.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Zoledronate

Primary outcome measure

A significant difference in serum type I collagen C-telopeptides (CTX) according to treatment group at day 7 of the study

Secondary outcome measures

Increased bone mineral density (BMD), measured at days 7, 90, 180 and 360

Overall study start date

20/04/2009

Completion date

31/12/2011

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

1. Aged 18 - 65 years (either sex) with a diagnosis of multiple sclerosis (MS)
2. Acute flare up requiring treatment with a corticosteroid
3. Able to attend for study investigations and assessments
4. Willing and able to provide informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Previous diagnosis of osteoporosis
2. Bone therapy within previous 12 months
3. Previous bisphosphonate therapy at any time
4. Associated disorder that may affect bone metabolism

- 5. Pregnancy
- 6. Breastfeeding

Date of first enrolment

20/04/2009

Date of final enrolment

31/12/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Academic Rheumatology

Bristol

United Kingdom

BS10 5NB

Sponsor information

Organisation

North Bristol NHS Trust (UK)

Sponsor details

c/o Margaret Stoddart

R&D Manager Governance

Coach House

Southmead Hospital

Westbury-on-Trym

Bristol

England

United Kingdom

BS10 5NB

Sponsor type

Hospital/treatment centre

Website

<http://www.nbt.nhs.uk/>

ROR

Funder(s)

Funder type

Industry

Funder Name

Novartis Pharmaceuticals (UK)

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?
HRA research summary			28/06/2023	No	No