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Zoledronate to prevent bone loss in acute multiple sclerosis

Submission date	Recruitment status	[ ] Prospectively registered
08/04/2009	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/05/2009	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/08/2014	Nervous System Diseases	[ ] Record updated in last year

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
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

Study type(s)
Treatment

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

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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre

Academic Rheumatology
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
North Bristol NHS Trust (UK)

ROR
https://ror.org/036x6gt55

Funder(s)

Funder type
Industry

Funder Name
Novartis 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?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes