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Prevention of bone loss following spinal cord injury

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/11/2010	Musculoskeletal Diseases	

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
N0209132504

Study information

Scientific Title

Study objectives
Do early interventions (drug or mechanical stimulation) reduce the risk of osteoporosis following spinal cord injury?

Please note that as of 16/04/10 this record has been updated and the information obtained from a recent publication of the results (details below). All updates can be found in the relevant field with the above update date.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 16/04/10: Ethical approval was obtained from the Royal National Orthopaedic Hospital NHS Trust ethics committee

Study design
Open label randomised controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Musculoskeletal Diseases: Osteoporosis

Interventions
Patients will be randomly assigned to either
1. Control group,
2. Group receiving zoledronate
3. Group receiving mechanical stimulation (vibration)
and receive the treatment over a 6 month period.
Bone Mineral Density and biochemical markers of bone metabolism will be assessed at the start of the study and at 3 and 6 months after intervention.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
1. Changes in Bone Mineral Density and biochemical markers of bone metabolism over time.
2. Difference between groups

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/08/2003

Completion date
01/08/2005

Eligibility

Key inclusion criteria
1. Patients admitted to Royal National Orthopaedic Hospital (RNOH) with a spinal cord injury

Added 16/04/10:
2. Female patients had to be postmenopausal, surgically sterile or willing to practice a medically acceptable form of birth control during the study period and for at least 12 months after study completion
3. All subjects gave written consent to take part in the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
14 (added 16/04/10)

Key exclusion criteria
Added 16/04/10:
1. Pregnant or breastfeeding
2. Previous history of allergic reaction to bisphosphonates
3. Previous history of iritis or uveitis
4. Significant renal impairment or evidence of vitamin D deficiency (serum 25-hydroxyvitamin D <25 nmol/L)

Date of first enrolment

01/08/2003

Date of final enrolment
01/08/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
RNOHT
Stanmore
United Kingdom
HA7 4LP

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

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?
Results article	results	01/01/2011		Yes	No