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Intravenous bisphosphonates in the prevention of osteoporosis associated with stroke

Submission date 02/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/08/2005	**Overall study status** Completed	
Last Edited 08/06/2011	**Condition category** Circulatory System	

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
LREC 01/245

Study information

Scientific Title

Study objectives
The aim of this study is to investigate whether reductions in bone mineral density (BMD) in the hemiplegic hip of stroke patients can be prevented with the early use of a single dose of intravenous zoledronate. The study consists of a randomised double-blinded placebo-controlled trial of intravenous zoledronate (4 mg) to prevent bone loss in hemiplegic patients with acute stroke. Bone mineral density in both hemiplegic and unaffected hips of hemiplegic patients will be assessed, and patients will be randomised to receive a single infusion of either 4 mg zoledronic acid or placebo within 35 days of acute stroke. Serial measurements of hip bone mineral density will be made at 6 and 12 months in addition to detailed assessments of stroke recovery, functional status and balance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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
Stroke and osteoporosis

Interventions
Intravenous zoledronate 4 mg versus placebo.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Zoledronate

Primary outcome measure
Bone mineral density at the hemiplegic hip 12 months following stroke.

Secondary outcome measures
1. Bone mineral density at the unaffected hip 12 months following stroke
2. Histomorphometric analysis of bone biopsies from stroke patients treated with zoledronate or placebo

Overall study start date
01/10/2001

Completion date
22/09/2005

Eligibility

Key inclusion criteria
For inclusion, males and females aged 40-89 will be approached as soon as possible after admission with first ever stroke. Patients will be eligible if they were previously independently walking, have clinical and computed tomography (CT) evidence of stroke (haemorrhagic or ischaemic), are unable to walk 1 week following stroke (Functional Ambulatory Category [FAC] 0 or 1) and can give written informed consent to the study.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
Exclusion criteria are as follows:
A. Not walking independently prior to stroke/previous stroke causing hemiplegia
B. Stroke not affecting the lower limb/FAC >1 at 1 week post stroke/posterior circulation stroke
C. Unconsciousness or terminal illness
D. Pre-existing dementia or cognitive impariment
E. Aphasia/significant language impairment
F. Renal/hepatic impairment
G. Aged <40 and >89
H. Prior treatment with a bisphosphonate, corticosteroids/known osteoporosis/unilateral bone disease affecting BMD/prior hip fracture or osteosynthetic material at the hip (e.g. hip replacement)
I. Unable to randomise and give infusion within 35 days of stroke (e.g. tertiary referrals from

another hospital)
J. Current treatment with an aminoglycoside antibiotic

Date of first enrolment
01/10/2001

Date of final enrolment
22/09/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Clinical Neurosciences
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details
Addenbrooke's Hospital
Hills Road
Cambridge
England
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CB2 2QQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
National Osteoporosis Society (UK) RG33985

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	01/05/2007		Yes	No