

# Intravenous bisphosphonates in the prevention of osteoporosis associated with stroke

<b>Submission date</b> 02/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/08/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/06/2011	<b>Condition category</b> Circulatory System	<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

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 impairment
- 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

United Kingdom

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?
<a href="#">Results article</a>	results	01/05/2007		Yes	No