ISRCTN57438091 https://doi.org/10.1186/ISRCTN57438091

# Intravenous bisphosphonates in the prevention of osteoporosis associated with stroke

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

**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**
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

## Study type(s)
Prevention

## 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(s)
Bone mineral density at the hemiplegic hip 12 months following stroke.

## Key secondary outcome(s))
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

## 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### 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
United Kingdom

England

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

# Sponsor information

**Organisation**
Cambridge University Hospitals NHS Foundation Trust (UK)

**ROR**
https://ror.org/04v54gj93

# Funder(s)

**Funder type**
Charity

**Funder Name**
National Osteoporosis Society (UK) RG33985

# 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? |
|---|---|---|---|---|---|
| Results article | results | 01/05/2007 | | Yes | No |