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# To assess the safety and feasibility of administering Dexamphetamine after stroke and its effect on cerebral and cardiac haemodynamics

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 26/08/2005 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 28/10/2005 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 17/09/2009 | 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
N/A

# Study information

### Scientific Title

### Acronym
STAR

### Study objectives
1. To study the safety and feasibility of administering dexamphetamine twice weekly in 42 patients with a recent ischaemic stroke, and its effect on motor impairment
2. To study the effect of dexamphetamine on cerebral and cardiac haemodynamics in stroke patients

### 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)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Ischaemic Stroke

### Interventions
Eligible patients who have provided consent will be randomly assigned to receive either dexamphetamine or placebo control. Dexamphetamine or placebo control will be administered orally twice a week with alternating 3 or 4 day separations. There will be a total of 10 doses covering a treatment period of 31 days. Further measurements of haemodynamics will be made

90 minutes after the first dose and immediately before, and 90 minutes after, the second dose. Measurements of the Barthel, Rankin and Scandinavian Neurological Stroke Scale (SNSS) will also be repeated 90 minutes after the second dose. Patients will remain as inpatients for the 7 days required. Xenon CT will be performed on selected patients (approx 8) to assess the dexamphetamine effect on cerebral perfusion before and 1 hour after the first administration.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Dexamphetamine

### Primary outcome measure
The safety, tolerabilty and feasibility of dexamphetamine in acute ischaemic stroke and its effect on motor impairment, cerebral and cardiac haemodynamics.

### Secondary outcome measures
At outcome (35 days) and follow up (90 days): Modified Rankin, Barthel Index, SNSS, Motricity Index, Grip Strength, Thumb-finding test, Sheffield aphasia screening, modified Mini-Mental State Examination (MMSE), Zung depression, EuroQUOL, 10-Hole Peg Test.

### Overall study start date
18/10/2000

### Completion date
31/03/2006

## Eligibility

### Key inclusion criteria
1. Clinical stroke 3-30 days post ictus
2. Ischaemic stroke on computed tomography (CT)/magnetic resonance imaging (MRI)
3. Motor weakness (Motricity Index arm 0-99 inclusive)
4. Patients expected to stay in hospital for a further 8 days

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
42

### Key exclusion criteria
1. Pre-morbid Barthel Index <12/20
2. Dementia
3. No enteral access in prescence of dysphagia
4. Moderate-severe hypertension (systolic blood pressure [BP] >160 or diastolic BP >100)
5. Clinical ischaemic heart disease, previous or current angina, myocardial infarction
6. Hyperexcitability or agitated states
7. Current hyperthyroidism
8. History of alcohol or drug abuse
9. Glaucoma
10. Predisposition to tics or Tourette Syndrome
11. Epilepsy or recent convulsions
12. Liver dysfunction (aspartate aminotransferase [AST] 3 x normal)
13. Renal dysfunction (creatinine >130)
14. Pregnancy and breastfeeding
15. Recent monoamine oxidase inhibitor (MAOI) usage
16. Porphyria

### Date of first enrolment
18/10/2000

### Date of final enrolment
31/03/2006

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
### University of Nottingham
Nottingham
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## Sponsor information

### Organisation
University of Nottingham (UK)

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### Sponsor type
University/education

### ROR
https://ror.org/01ee9ar58

## Funder(s)

### Funder type
University/education

### Funder Name
University of Nottingham (UK)

### Alternative Name(s)

### Funding Body Type
Private sector organisation

### Funding Body Subtype
Universities (academic only)

### Location
United Kingdom

## 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 | 01/08/2007 | | Yes | No |