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A pilot study to estimate the effect-size and possible selection criteria for dexamphetamine treatment during rehabilitation after acute stroke

Submission date 12/09/2003	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 12/09/2003	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 27/07/2009	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

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

N0050119120

Study information

Scientific Title

Study objectives
Dexamphetamine has repeatedly been shown to enhance recovery after experimental brain injury in animal models. Our aim is to see whether dexamphetamine, given with rehabilitation treatment early after a stroke, is able to improve the recovery of limb weakness and, if so, to see which groups of patients respond best.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double blind placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Stroke

Interventions
This is a placebo-controlled, double-blind, randomised pilot study based within two rehabilitation stroke units. Eligible patients will be randomised to receive either dexamphetamine or placebo, with two-thirds of the subjects receiving dexamphetamine. The medication will be given as a capsule by mouth about 1 h before a 60 min session of rehabilitation. The rehabilitation treatment will be provided in the standard way except that rehabilitation sessions will be timed to occur during the period of peak effect of the study medication.

Measurements of recovery will assess residual weakness and disability and will be made by the same health-trained research assistant at 3 and 6 weeks after recruitment and at 3 months after the stroke.

Added 27/07/09: trial was stopped due to lack of funding.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
dexamphetamine

Primary outcome measure
The extent to which a subject's weakness has recovered at 3 months after the stroke. Interim assessments will occur at 3 and 6 weeks after beginning the trial medication. Assessment of recovery will document residual weakness of the affected arm, trunk and leg (using the Rivermead motor assessment scale) and the subject's degree of independence in basic activities of daily living (using the Barthel Index). In parallel, the subjects mood state will be assessed for depression and lack of motivation.

Secondary outcome measures
Not provided at time of registration

Overall study start date
16/10/2002

Completion date
16/10/2004

Reason abandoned (if study stopped)
Lack of funding

Eligibility

Key inclusion criteria
All patients aged 18 years and over newly admitted to the stroke units in Bradford and Leeds will be assessed by a research assistant for potential recruitment.
Eligible subjects will
1. have had a new stroke resulting in a right or left-sided weakness of sufficient severity to require an anticipated minimum 4-week stay on the stroke unit.
2, have a Computed Tomography (CT) scan to exclude intracranial haemorrhage
3. be medically stable and able to participate in daily rehabilitation.

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. unable to understand language as a result of stroke
2. any memory impairment (pre-existing or as a consequence of the stroke)
3. stable heart disease and untreated high blood pressure
4. any psychiatric treatment within the past 5 years or a past history of drug or alcohol dependence.

Date of first enrolment
16/10/2002

Date of final enrolment
16/10/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Care of the Elderly
Bradford
United Kingdom
BD5 0NA

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall

London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Bradford Hospitals NHS Trust (UK)

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