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Amphetamine for stroke recovery: a clinical and magnetic resonance imaging study

Submission date	Recruitment status	[ ] Prospectively registered
30/03/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/03/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/11/2009	Circulatory System	[ ] 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
MCT-38134

Study information

Scientific Title

Study objectives
Hypothesis:
Clinical recovery, assessed by validated scales of neurologic impairment and disability at standardised times, will be significantly enhanced in patients recovering from hemiparetic stroke, receiving Amphetamine (AMPH) coupled with rehabilitation versus placebo coupled with rehabilitation.

Objective:
This project aims to determine whether AMPH paired with rehabilitative training can promote adaptive neuroplasticity and improve clinically-meaningful outcomes in patients recovering from hemiparetic stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Research Ethics Board of Sunnybrook & Women's College Health Science Centre (Canada) on the 9th November 1999 (ref: 214-1999).

Study design
Multicentre, two-arm, randomised parallel group placebo trial with participant, investigator, caregiver, outcome assessor, and data analyst blinding.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
10 mg amphetamine followed 90 minutes later by one hour physiotherapies, starting five to ten days post stroke, every three to four days for ten drug therapy sessions, versus a matched placebo.

Please note that this trial is now completed.

Contact for public queries:
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Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Recovery of hemiparesis measured by the Fugl Meyer Motor Assessment at 13 time points up to three months.

Secondary outcome measures
All secondary outcomes are measured at baseline, six weeks, and at three months:
1. National Institute of Health Stroke Scale (NIHSS)
2. Western Aphasia Battery (WAB)
3. Sunnybrook Neglect Assessment Procedure (SNAP)
4. Montgomery/Ashberg Depression Rating Scale
5. Apathy Scale
6. Structured Clinical Interview for Diagnostic and Statistical Manual of mental disorders fourth edition (SCID-DSM-IV)
7. Ideomotor Praxis
8. Chedoke-McMaster Stroke Assessment
9. Clinical Outcomes Variable Scale (COVS)
10. Stroke Rehabilitation Assessment of Movement (STREAM)
11. Barthel Index Scale
12. Functional Independence Measure (FIM)
13. Modified Rankin Scale (MRS)
14. Stroke Impact Scale (SIS)
15. Chedoke Arm and Hand Activity Inventory
16. Mini Mental State Examination (MMSE)

Overall study start date
01/02/2000

Completion date
31/12/2002

Eligibility

Key inclusion criteria
1. Female or male, 30 to 65 year old
2. Ischaemic hemispheric stroke patients with moderate to severe hemiparesis
3. Medically able to participate in a rehabilitation program and expected to survive three months post-stroke
4. Pre-morbid modified Rankin score zero or one
5. Informed consent from patient or substitute decision maker

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
71

Key exclusion criteria
1. Brainstem or cerebellar stroke
2. Primary intracerebral haemorrhage
3. Pre-existing neurologic deficit (e.g. from prior stroke) that could interfere with assessments
4. Pregnancy and lactation
5. Prior history of dementia
6. Known hypersensitivity to sympathomimetic amines
7. Unstable cardiac arrhythmia or hypertension not controlled by medication (greater than 170 /105 mmHg)
18. History of psychosis or tic disorder
19. Untreated hyperthyroidism
20. Concomitant use of alpha-adrenergic antagonists or agonists
21. Concomitant use of monoamine oxidase inhibitors or use within the preceding 14 days

Date of first enrolment
01/02/2000

Date of final enrolment
31/12/2002

Locations

Countries of recruitment
Canada

Study participating centre

Sunnybrook Health Sciences Centre
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Sponsor information

Organisation
Sunnybrook Health Sciences Centre (Canada)

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Sponsor type
Hospital/treatment centre

Website
http://www.sunnybrook.ca/

ROR
https://ror.org/03wefcv03

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca/ (ref: MCT-38134)

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