

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

Submission date 30/03/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/03/2007	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 19/11/2009	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

Protocol serial number
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).

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Ontario

Canada

M4N 3M5

Sponsor information**Organisation**

Sunnybrook Health Sciences Centre (Canada)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration