

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

<b>Submission date</b> 30/03/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/03/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 19/11/2009	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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**  
Ontario  
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## **Sponsor information**

### **Organisation**

Sunnybrook Health Sciences Centre (Canada)

### **Sponsor details**

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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