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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre University of Nottingham

Nottingham United Kingdom NG5 1PB

Sponsor information

Organisation

University of Nottingham (UK)

ROR

https://ror.org/01ee9ar58

Funder(s)

Funder type

University/education

Funder Name

University of Nottingham (UK)

Alternative Name(s)

The University of Nottingham

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2007		Yes	No