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

Submission date
26/08/2005

Recruitment status
No longer recruiting

Registration date
28/10/2005

Overall study status
Completed

Last Edited
17/09/2009

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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