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The RIGHT Trial: Rapid Intervention with Glyceryl trinitrate (GTN) in Hypertensive stroke Trial

Submission date 18/02/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/05/2008	**Overall study status** Completed	
Last Edited 21/08/2015	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims.
The first few hours following a stroke are critical as there may be brain cells that are at the risk of dying but may still be saved. High blood pressure following stroke is common and may impact negatively on the survival of these brain cells. Trials that have assessed the effect of lowering blood pressure following a stroke however have not shown any benefit, but this may be because treatment was often delayed by several hours by the time patients were seen in the hospital. Our goal is to assess the feasibility of using the ambulance services to deliver acute stroke treatments. In this study, paramedics will treat patients with glyceryl trinitrate (GTN), a drug that dilates blood vessels and reduces blood pressure, within 4 hours of stroke. The study will also provide important information on the effects of GTN in very acute strokes.

Who can participate?
We aim to recruit 80 patients with a stroke who are within 4 hours of onset and also have high blood pressure. Only patients who are seen by our trained paramedics in the Nottingham City, UK district will be included in the study.

What does the study involve?
Patients will be randomly allocated to receive either a dressing containing GTN or a standard gauze dressing. Paramedics will then measure the patients' blood pressure 10-15 minutes after the dressing is applied. Once in the hospital more detailed information will be given and if patients agree to continue in the study, the treatment will be continued daily for 7 days. Researchers will check the blood pressure every day and perform clinical assessments after completion of 7 days treatment. The final follow up is at 3 months and a member of the research team will do a face to face assessment of the patient, check on their condition, and ask questions about mobility, mood, memory and quality of life.

What are the possible benefits and risks of participating?
There may be no direct benefit for patients taking part in the study. The information we get from patients' involvement may benefit other people who may have a stroke in the future. All drugs have the possibility of side effects. The side effects from GTN are generally mild. They can

include headache, low blood pressure and dizziness. Patients will be monitored and asked to inform the treating doctor or member of the research team if they feel they have a reaction to the medication.

Where is the study run from?
The Division of Stroke, University of Nottingham.

When is the study starting and how long is it expected to run for?
The study started recruitment in February 2010 and is expected to run until the end of December 2011.

Who is funding the study?
The Nottingham University Hospitals NHS Trust Research and Development, The Division of Stroke, University of Nottingham.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2007-004766-40

Protocol serial number
N/A

Study information

Scientific Title
Determining the potential of ambulance-based randomised controlled trials in patients with hyperacute stroke: assessment of glyceryl trinitrate in lowering blood pressure

Acronym
RIGHT

Study objectives
1. To assess the feasibility of performing an ambulance-based trial in patients with hyperacute stroke, a key question for the future testing of potential interventions aimed at neuroprotection and physiological control
2. To assess the effect of glyceryl trinitrate (GTN) on blood pressure (BP) in this setting

On 05/11/2012 the overall trial end date was changed from 31/12/2011 to 15/03/2012.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Nottingham research ethics committee, 08/04/2009, ref: 09/H0408/5

Study design
Single-blind randomised controlled trial with blinded outcome assessment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute stroke

Interventions
Transdermal GTN (5 mg) or no patch.
Total duration of treatment: 7 days
Total duration of follow up: 90 days

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Glyceryl trinitrate

Primary outcome(s)

To assess the feasibility of using the ambulance service to test and deliver treatment for stroke in the hyperacute setting, will be measured as effects of GTN on blood pressure at 2 hours post-treatment.

Key secondary outcome(s))

Current secondary outcome measures as of 05/11/2012:
Haemodynamic outcomes
1. BP and heart rate (HR) at 15 minutes (in ambulance), 120 minutes (at hospital) and on days 2-7.
BP/HR derivatives were calculated as follows:
Pulse pressure (PP) = systolic BP (SBP) - diastolic BP (DBP)
Rate pressure product = SBP x HR
2. Central BP and aortic compliance (Augmentation Index) were at 120 minutes

Clinical outcomes
1.Impairment (Scandinavian Stroke Scale, SSS) at 2 hours and day 7.
2. Other measurements at day 7 included
2.1. Recurrence
2.2. Death
2.3. Headache
2.4. Hypotension
2.5. Neurological deterioration (defined as a 5 point reduction in the SSS from Day 1 to Day 7).
3. Final clinical functional outcomes were recorded at day 90 including
3.1. Dependency (modified Rankin Scale, mRS),
3.2. Disability (Barthel Index, BI),
3.3. Cognition (Mini Mental State Examination, MMSE),
3.4. Mood (Zung Depression Index, ZDI), and
3.5. Quality of life (EuroQoL, as EQ-5D and EQ-VAS).

Ambulance trial logistics outcomes
1. Recruitment rate
2. Protocol violations
3. Final diagnosis
4. Timings between ictus, paramedic arrival and departure
5. Arrival at hospital

Previous secondary outcome measures until 05/11/2012:
To assess the effects of GTN on:
1. Blood pressure
2. Pulse pressure (PP)
3. Rate pressure product (RPP)
4. Surrogate markers of efficacy in blood in the hyperacute setting

Measured in hospital, day 7/discharge/death, and day 90.

Completion date

15/03/2012

Eligibility

Key inclusion criteria

1. Adult patients of either sex; greater than 40 years of age
2. Paramedic assessment of stroke on basis of positive Face & Arm weakness and Speech abnormality Test (FAST) in the context of a call to a patient with a possible acute stroke
3. Event less than 4 hours of onset (sleep stroke - onset as bed time)
4. High systolic BP (greater than 140 mmHg)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. No consent/assent is available
2. GTN is indicated (e.g. concurrent angina)
3. GTN is contraindicated (e.g. dehydration, hypovolaemia)
4. Aged less than 40 years
5. Coma; Glasgow Coma Scale (GCS) score less than or equal to 8
6. History of seizures
7. Non-ambulatory pre-morbidly (modified Rankin scale of greater than 2)
8. Hypoglycaemia (if glucose tested)
9. Patients from a nursing home

Date of first enrolment
01/02/2010

Date of final enrolment
01/12/2011

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
Nottingham University Hospitals NHS Trust (Research &Development Pump Priming competition)

Funder Name
The Division of Stroke, University of Nottingham

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2013		Yes	No
Protocol article	protocol	01/11/2012		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes