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Rapid intervention with glyceryl trinitrate in hypertensive stroke trial-2

Submission date 04/03/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/03/2015	**Overall study status** Completed	
Last Edited 23/04/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Stroke is a serious, life-threatening medical condition that usually happens when a blood clot or haemorrhage cuts of the blood supply to an area of the brain. Symptoms vary according to how much of the brain is affected and where in the brain the stroke occurs, but includes paralysis, muscle weakness and speech difficulties. A stroke can also have an impact on the sufferers emotions and can lead to anxiety, depression and personality changes. It is thought that lowering blood pressure quickly after the stroke could have a beneficial effect on a patient's recovery. Therefore, this study aims to find out whether giving patients who are suspected of having a stroke, a 5mg transdermal glyceryl trinitrate (GTN) patch (a commonly used drug in patients with heart disease) as soon as possible after stroke, and then daily for the next three days, improves outcome.

Who can participate?
Adult patients presenting to paramedics as having a stroke. The stroke should have occurred no more than 4 hours ago and the patients systolic BP >=120 mmHg

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given GTN patches for 4 days. Those in group 2 are given sham (dummy) patches for 4 days. The patches are unmarked and are covered with a gauze dressing so that participant, relatives and staff who are not putting the patches on don't know what treatment has been given. The paramedic and hospital staff putting the patch on do know what treatment the patient has. Paramedics obtain consent and put the first patch on, either in the participant's home or in the ambulance, before they take the patient to the hospital. The participant has all the care they would normally get for their stroke. In addition, they have a second CT scan on Day 2. They are telephoned 3 months and then 1 year after their stroke and asked various structured questions to determine their recovery. When settled in hospital, participants may be asked to agree to some extra procedures or give extra blood samples for research by a member of the research team. Participants do not need to take part in any of this additional research.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Nottingham City Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2015 to February 2018

Who is funding the study?
British Heart Foundation (UK)

Who is the main contact?
Mrs Diane Havard

Contact information

Type(s)
Public

Contact name
Mrs Diane Havard

Contact details
Nottingham City Hospital
Division of Stroke Medicine
The University of Nottingham
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Nottingham
United Kingdom
NG5 1PB

Additional identifiers

EudraCT/CTIS number
2015-000115-40

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18362

Study information

Scientific Title
Rapid intervention with glyceryl trinitrate in hypertensive stroke trial-2 (RIGHT2): assessment of safety and efficacy of transdermal glyceryl trinitrate, a nitric oxide donor, and of the feasibility of a multicentre ambulance-based stroke trial

Acronym

RIGHT-2

Study objectives
This study aims to find out whether giving patients who are suspected of having a stroke, a 5mg transdermal glyceryl trinitrate (GTN) patch (a commonly used drug in patients with heart disease) as soon as possible after stroke, and then daily for the next three days, improves outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
15/EM/0055

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Stroke; Subtopic: Acute Care; Disease: In hospital study

Interventions
Transdermal Glyceryl Trinitrate patch 5mg, daily for 4 days or sham patch for 4 days.

Intervention Type
Drug

Phase
Phase III

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

Primary outcome measure
Death/dependence/independence: 7-level modified Rankin Scale 90 days after stroke

Secondary outcome measures
N/A

Overall study start date
01/05/2015

Completion date
31/10/2018

Eligibility

Key inclusion criteria
1. Patients presenting to paramedics in context of 999 ambulance call for ‘stroke’
2. Age 18 years or more (there is no maximum age)
3. ‘Face/Arm/Speech’ Time (FAST) score >1
4. Time <=4 hours of onset
5. Systolic BP >=120 mmHg
6. Have provided informed consent, or a relative/paramedic has provided proxy consent
7. Paramedic is trained in RIGHT2 procedures, is from a participating ambulance station and will take patient to a participating comprehensive/primary stroke centre

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 850; UK Sample Size: 850

Total final enrolment
1149

Key exclusion criteria
1. Patient at a Nursing or Care Home
2. Glucose (BM stix) <2.5 mmol/l
3. Glasgow Coma Scale <8
4. Witnessed seizure/fit at presentation
5. Known life expectancy <6 months
6. Known to have taken a PDE5 inhibitor, such as sildenafil, in previous day before stroke
7. Known sensitivity to Transiderm Nitro patch
8. Known sensitivity to Duoderm hydrocolloid dressing

Date of first enrolment

01/05/2015

Date of final enrolment
01/02/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham City Hospital
Division of Stroke Medicine
Nottingham
United Kingdom
NG5 1PB

Sponsor information

Organisation
University of Nottingham

Sponsor details
Research Innovation Services
Kings Meadow Campus
Lenton Lane
Nottingham
England
United Kingdom
NG7 2NR

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The results will be published in February 2019.

Intention to publish date
28/02/2019

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	09/03/2019		Yes	No
Protocol article	protocol	01/02/2019	28/11/2019	Yes	No
Other publications	baseline characteristics	01/04/2019	22/01/2020	Yes	No
Results article	results	01/11/2019	31/03/2020	Yes	No
Results article		21/11/2022	22/11/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article	1 year post randomisation	27/06/2023	14/08/2023	Yes	No
Results article	Narrative data	29/11/2023	01/12/2023	Yes	No

Results article	Prehospital transdermal glyceryl trinitrate for ultra-acute ischaemic stroke: data from the RIGHT-2 randomised sham-controlled ambulance trial	08/06/2023	23/04/2025	Yes	No