

Rapid intervention with glyceryl trinitrate in hypertensive stroke trial-2

Submission date 04/03/2015	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 05/03/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/04/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

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 off 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 sufferer's 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 patient's 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

Clinical Trials Information System (CTIS)
2015-000115-40

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

N/A

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

Study participating centre

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

Sponsor information

Organisation

University of Nottingham

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation

Alternative Name(s)

The British Heart Foundation, the_bhf, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

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
Results article	results	01/11/2019	31/03/2020	Yes	No
Results article		21/11/2022	22/11/2022	Yes	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
Protocol article	protocol	01/02/2019	28/11/2019	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	baseline characteristics	01/04/2019	22/01/2020	Yes	No