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Specialist pre-hospital redirection for ischaemic stroke thrombectomy (SPEEDY)

Submission date
25/07/2022

Recruitment status
Recruiting

Registration date
12/08/2022

Overall study status
Ongoing

Last Edited
12/08/2022

Condition category
Circulatory System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Stroke is a common medical emergency and time-critical treatments reduce the chance of disability or death. About 1 in 10 patients are suitable for an emergency operation to remove blood clots blocking large arteries in the brain (known as thrombectomy) which greatly improves their chances of recovery. However, this operation is only available at specialist regional hospitals and unless patients live nearby, they are first admitted to their local hospital and must be transferred for treatment. A transfer typically delays thrombectomy by at least 90 minutes and reduces its benefit. Faster treatment might occur if patients could attend specialist regional hospitals directly but at present no accurate assessment or portable test exists to guide ambulance staff to make a confident diagnosis of stroke, or to determine that thrombectomy is needed.
In an earlier research project, a specialist prehospital redirection pathway was developed which involves communication between ambulance practitioners and specialist hospital thrombectomy staff to decide whether the emergency operation is likely to be required, followed by direct admission to the specialist hospital if this is the case. This study will now test the impact of this new pathway.

Who can participate?
All suspected and confirmed acute stroke patients from participating geographical regions will be involved

What does the study involve?
Ambulance stations (work bases for ambulance practitioners) or ambulance staff teams will be assigned at random to use the new pathway or to continue with current standard care when attending suspected stroke patients. Data will be collected about thrombectomy treatments and other aspects of emergency medical care received which will be compared between the two groups.

What are the possible benefits and risks of participating?
This study is testing whether a new emergency care pathway improves access to thrombectomy treatment for some people. The pathway may result in faster treatment and better recovery after stroke but this is not yet known.

Where is the study run from?
Newcastle University (UK)

When is the study starting and how long is it expected to run for?
August 2021 to July 2026

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Lisa Shaw, lisa.shaw@newcastle.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Lisa Shaw

Contact details
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
312053

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53148, IRAS 312053

Study information

Scientific Title

Specialist pre-hospital redirection for ischaemic stroke thrombectomy (SPEEDY): a cluster randomised controlled trial with included health economic and process evaluations

Acronym
SPEEDY

Study objectives
The aim of the study is to determine the clinical and cost-effectiveness of a novel specialist prehospital redirection pathway intended to facilitate thrombectomy treatment for acute stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/06/2022, North East - Newcastle & North Tyneside 1 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048091; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 22/NE/0103

Study design
Randomized; Interventional; Design type: Process of Care, Complex Intervention, Management of Care

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Suspected and confirmed acute stroke

Interventions
This research study is a multicentre cluster randomised controlled trial with included health economic and process evaluations. The intervention to be evaluated is a new pathway which involves communication between ambulance and specialist hospital staff to select patients for direct admission to a specialist regional hospital who are likely to need emergency thrombectomy treatment. Clusters will be ambulance stations (work bases for ambulance

practitioners) or ambulance staff teams which prior to the start of the study will be assigned at random to use the new pathway or to continue with current standard care when attending suspected stroke patients.

Intervention Type
Other

Primary outcome measure
Data collected from routine healthcare sources throughout the study period:
1. Thrombectomy rate
2. The time from stroke symptom onset to thrombectomy (when thrombectomy is received)

Secondary outcome measures
Data collected from routine healthcare sources throughout the study period:
1. Key emergency care time intervals
2. Receipt of and time to thrombolysis treatment
3. Stroke severity 24 hours post reperfusion treatment (NIHSS)
4. Length of hospital stay
5. Dependency at discharge (mRS)

Overall study start date
01/08/2021

Completion date
31/07/2026

Eligibility

Key inclusion criteria
1. An ambulance practitioner from a randomised station/team attended the incident
2. Conveyance was to either a local stroke hospital which refers patients to the participating specialist regional hospital, or directly to the participating specialist regional hospital
3. Acute stroke was suspected by the attending ambulance practitioner (i.e. Face, Arm, Speech Test (FAST) positive or any observed new focal neurological symptoms which indicated acute stroke according to the ambulance practitioner’s clinical judgement) OR acute stroke was diagnosed following arrival at a participating hospital irrespective of ambulance practitioner initial judgement of symptom cause

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 80000; UK Sample Size: 80000

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/09/2022

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North East Ambulance Service NHS Ft
Bernicia House
Goldcrest Way
Newcastle upon Tyne
United Kingdom
NE15 8NY

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
North West Ambulance Service NHS Trust
Ladybridge Hall
399 Chorley New Road
Bolton
United Kingdom
BL1 5DD

Study participating centre

Lancashire Teaching Hospitals NHS Foundation Trust
Royal Preston Hospital
Sharoe Green Lane
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Salford Royal NHS Foundation Trust
Salford Royal
Stott Lane
Salford
Manchester
United Kingdom
M6 8HD

Study participating centre
West Midlands Ambulance Service University NHS Foundation Trust
Millennium Point
Waterfront Business Park
Dudley Road
Brierley Hill
United Kingdom
DY5 1LX

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
South Western Ambulance Service NHS Foundation Trust
Abbey Court
Eagle Way
Exeter
United Kingdom
EX2 7HY

Study participating centre
North Bristol NHS Trust
Southmead Hospital
Southmead Road
Westbury-on-trym
Bristol
United Kingdom
BS10 5NB

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
c/o Aaron Jackson
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Regent Farm Road
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NE3 3HD
+44 (0)1912825789
aaron.jackson@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR202361

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/07/2027

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No