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Prehospital biomarker and phone call-based detection for ischaemic stroke thrombectomy

Submission date
03/07/2025

Recruitment status
Recruiting

Registration date
11/07/2025

Overall study status
Ongoing

Last Edited
11/07/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
For some people who have a serious type of stroke called 'large vessel occlusion stroke (LVO)', an emergency operation called 'thrombectomy' is needed to remove a blood clot blocking an artery in the brain. The faster the thrombectomy is received, the better the chances of recovery. However, thrombectomy is very specialised and only available in certain regional hospitals.

Currently there are no specific assessments or tests that ambulance staff can use to work if LVO stroke is happening or if an urgent operation may be needed. Consequently, most patients with LVO stroke suitable for thrombectomy must be transferred to a specialised regional hospital after tests (e.g brain scans) at their local hospital. This takes extra time to get to thrombectomy. This research is evaluating whether a new ambulance assessment is sufficiently accurate for future use. The assessment is for identifying people who have LVO stroke and may need thrombectomy. It consists of a fingerprick blood test (called 'LVOne test') and telephone communication between ambulance and hospital staff. The fingerprick test measures two blood chemicals called 'd-dimer'and 'GFAP' and earlier research conducted in hospitals suggests that together these chemicals indicate LVO stroke. Other previous research has demonstrated that ambulance to hospital communicated clinical information has value for recognising people who need thrombectomy.

Who can participate?
Adults (aged 18 years and over) considered to be suffering from an acute stroke when assessed by ambulance staff.

What does the study involve?
Participants will undergo the new ambulance assessment which consists of a portable fingerprick blood test and telephone communication between ambulance and hospital staff. Following arrival at hospital, data will be collected about health symptoms, tests conducted, and treatments provided. Data will be analysed to determine how well the new ambulance assessment works to identify people with LVO stroke who may need thrombectomy.

What are the possible benefits and risks of participating?
This research is being conducted to determine whether a new ambulance assessment is

sufficiently accurate for future use. There are no direct benefits to individuals who take part in the study, however it is hoped that care for future patients will be improved as a result of the research.

Where is the study run from?
North East Ambulance Service (UK)
Northumbria Specialist Emergency Care Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2025 to June 2026

Who is funding the study?
Small Business Research Initiative for Healthcare (UK)

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

Contact information

Type(s)
Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
356128

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS68443

Study information

Scientific Title
PRehospital biomarker and phoNe call-based detection for ischaemic stroke thrombecTOmy

Acronym
PRONTO

Study objectives
The primary objective is to determine the diagnostic accuracy of the LVOne test for identification of large vessel occlusion stroke, when the test is used in the pre-hospital setting.

A secondary objective is to determine the diagnostic accuracy of the LVOne test combined with specific clinical information communicated from ambulance practitioners to stroke teams for identification of patients suitable for direct admission to a thrombectomy centre.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 16/05/2025, North East Newcastle and North Tyneside 1 (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 2071048384; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 25/NE/0109

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital, Paramedicine

Study type(s)
Diagnostic

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 stroke

Interventions
This prospective observational cohort study is evaluating a lateral flow fingerprick blood test (called 'LVOne test') in combination with telephone communication of clinical information between ambulance and hospital staff. The lateral flow fingerprick test measures blood levels of d-dimer and glial fibrillary acidic protein (GFAP).

Intervention Type
Other

Primary outcome measure
Sensitivity, specificity, positive and negative predictive values for identification of LVO stroke calculated from the fingerprick blood test result and reference standard tests

Secondary outcome measures
Secondary objectives/analyses will examine the accuracy of the fingerprick test combined with specific clinical information communicated from ambulance practitioners to stroke teams for identification of patients suitable for direct admission to a thrombectomy centre

Overall study start date
01/03/2025

Completion date
30/06/2026

Eligibility

Key inclusion criteria
Study trained ambulance practitioners will be asked to undertake the LVOne test and communicate clinical information to hospital on patients that fulfil the following criteria:
1. Being attended in the community after a 999 call
2. Being attended in a geographical region where ambulance conveyance is to a hospital participating in the study
3. Aged 18 years or over
4. Alert, Responds to Voice or Responds to Pain on the AVPU scale
5. New acute stroke suspected
6. FAST clinical symptom score of ≥ 1
7. Stroke symptoms begun within the last 6 hours (i.e. onset time is known and within the last 6 hours or the patient is known to have been symptom free within the last 6 hours)
8. Not been an inpatient in hospital or had an emergency hospital attendance within the last 7 days

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
496

Key exclusion criteria
Been an inpatient in hospital or had an emergency hospital attendance within the last 7 days

Date of first enrolment
21/07/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
North East Ambulance Service
Bernicia House
Goldcrest Way
Newburn Riverside

Newcastle Upon Tyne
United Kingdom
NE15 8NY

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

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North Tyneside General Hospital
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NE29 8NH
+44 (0)1912934087
peta.heslop@northumbria-healthcare.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.northumbria.nhs.uk/

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Government

Funder Name
Small Business Research Initiative for Healthcare (UK)

Results and Publications

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

Intention to publish date
31/12/2026

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