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Evaluation of a new fingerprick blood test for the identification of serious stroke

Submission date 17/04/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 02/05/2023	**Overall study status** Completed	
Last Edited 16/06/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Large vessel occlusion (LVO) stroke is a serious type of stroke caused by a blood clot blocking a large artery in the brain. For some people with LVO, an emergency operation (thrombectomy) to remove the blood clot improves the chances of recovery. However, the emergency operation is only available in specialist regional hospitals and most people must be transferred from their local hospital after a brain scan has been done to confirm the diagnosis. This results in delays to the emergency operation which can decrease the chance of recovery. Recently, a new portable fingerprick blood test has been developed which may be able to diagnose a likely LVO stroke. This study is assessing how well this new test works. If this new test works well, it could be done in ambulances in the future and people could then be taken directly to a regional hospital, saving time and reducing delays before treatment.

Who can participate?
Adults (aged 18 years and over) following emergency arrival at hospital who were assessed by ambulance personnel to be suffering from an acute stroke.

What does the study involve?
On arrival at hospital, participants will have the new fingerprick test, and data will be collected about the results of routine tests which are conducted to investigate a possible stroke. The new test result will be compared with routine tests to determine how well it works to diagnose likely LVO stroke.

What are the possible benefits and risks of participating?
This research is being conducted to determine if the new fingerprick test may be useful for identifying LVO stroke. 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 this research.

Where is the study run from?
1. Royal Victoria Infirmary (UK)
2. Northumbria Specialist Emergency Care Hospital (UK)
3. University Hospital of North Durham (UK)
4. Royal Blackburn Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2022 to June 2025

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)
Scientific

Contact name
Dr Lisa Shaw

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
323968

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 55630, IRAS 323968

Study information

Scientific Title
Rapid Assay Diagnostic for Acute stroke Recognition (RADAR)

Acronym
RADAR

Study objectives
The primary objective is to determine the diagnostic accuracy of a new portable fingerprick blood test for the identification of large vessel occlusion (LVO) stroke.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/03/2023, North East - Newcastle & North Tyneside 2 Research Ethics Committee (NHS BT Blood Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear, NE2 4NQ, UK; +44 (0)2071048091; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 23/NE/0043

Study design
Observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

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

Interventions
This research project is a prospective observational cohort study to evaluate the diagnostic accuracy of a new fingerprick blood test for the identification of LVO stroke.

The fingerprick test measures blood levels of d-dimer and glial fibrillary acidic protein (GFAP).

Intervention Type
Other

Phase
Not Specified

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

Key secondary outcome(s))
Secondary objectives/analyses will examine the accuracy of the fingerprick test using different analysis populations

Completion date
30/06/2025

Eligibility

Key inclusion criteria

1. Aged 18 years or over
2. Arrived at the study hospital by emergency ambulance
3. New acute stroke suspected by ambulance personnel before hospital arrival
4. FAST clinical symptom score is ≥1 (as determined by hospital staff)
5. Stroke symptoms are known to have begun within the last 6 hours OR the patient was last known to be well between 6 and 24 hours ago (times determined by hospital specialist staff)
6. Blood sampling can be undertaken prior to any reperfusion treatments
7. Routine brain imaging is intended to be urgently performed

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
608

Key exclusion criteria
1. Already assessed at another hospital and ambulance admission is a transfer for continuing care
2. Assigned a recent previous (within the last 4 weeks) diagnosis of deep vein thrombosis, pulmonary embolism, arterial embolism, stroke, TIA, long bone fracture, major trauma, any surgery under general anaesthesia (these diagnoses may have resulted in elevated d-dimer)
3. Suffered a recent previous (within the last 4 weeks) head injury which lead to hospital attendance (this event may have resulted in elevated GFAP)
4. Stroke symptoms are known to have begun greater than 6 hours ago

Date of first enrolment
01/06/2023

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

Study participating centre
Northumbria Specialist Emergency Care Hospital
Northumbria Way
Cramlington
United Kingdom
NE23 6NZ

Study participating centre
University Hospital of North Durham
North Road
Durham
United Kingdom
DH1 5TW

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
St George's Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
New Cross Hospital
Wolverhampton Road
Heath Town

Wolverhampton
United Kingdom
WV10 0QP

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Government

Funder Name
Small Business Research Initiative for Healthcare

Results and Publications

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?
Protocol article		09/08/2024	12/08/2024	Yes	No