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Improving stroke diagnosis: A study using blood tests and clinical information to quickly identify stroke types in suspected stroke patients

Submission date 27/01/2025	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/02/2025	**Overall study status** Ongoing	
Last Edited 10/09/2025	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Stroke is a leading cause of death and disability worldwide. Early and accurate diagnosis of stroke subtypes, such as bleeding in the brain (intracerebral haemorrhage, ICH) or a blocked blood vessel (large vessel occlusion, LVO), is critical to ensuring timely treatment and better outcomes. Current tools like the Face Arm Speech Test (FAST) are unable to reliably identify these subtypes, leading to delays in care. This study aims to develop and test a new diagnostic tool that combines clinical observations with a quick blood test (the LVOne test) to improve the diagnosis of stroke subtypes shortly after hospital arrival.

Who can participate?
Adults aged 18 or older who are brought to the hospital by ambulance with symptoms of a possible stroke that started within the last six hours are eligible to participate. Patients who have had recent injuries or conditions that could affect the test results may not be eligible.

What does the study involve?
Participants will have a small blood sample taken through a finger prick and, when possible, an additional sample from a routine blood draw. The blood samples will be tested using the LVOne test to measure levels of specific markers associated with stroke subtypes. Clinical data and brain imaging results will also be collected. The results of the blood test will not influence the patient’s treatment but will be compared to final diagnoses to evaluate the tool's accuracy.

What are the possible benefits and risks of participating?
There are no direct benefits to participants, but the study may improve future stroke diagnosis and care. Risks are minimal, with a small chance of discomfort or bruising from the finger prick or additional blood samples.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
May 2024 to December 2026

Who is funding the study?
The study is funded by the Translation Manchester Accelerator Awards and the University of Manchester (UK)

Who is the main contact?
Prof Adrian Parry-Jones, adrian.parry-jones@manchester.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Adrian Parry-Jones

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
351335

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
MR/X502868/1

Study information

Scientific Title
DIAGnosis using NOvel technology for Subtypes In Stroke (DIAGNOSIS study): performance evaluation

Acronym
DIAGNOSIS

Study objectives
Combining clinical features with point-of-care biomarker tests (GFAP and D-dimer) can improve the prehospital differentiation of stroke subtypes, specifically intracerebral hemorrhage (ICH) and large vessel occlusion (LVO), from other suspected stroke cases. This approach has the potential to enable more targeted and timely interventions, improving patient outcomes and resource allocation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/07/2025, Yorkshire & The Humber - Leeds West Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, Newcastle upon Tyne, NE2 4NQ, United Kingdom; 0207 1048053, 0207 104 8272, 02071048100; leedswest.rec@hra.nhs.uk), ref: 25/YH/0102

Study design
Observational diagnostic accuracy study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Differentiation of intracerebral hemorrhage (ICH) and large vessel occlusion (LVO) from other suspected stroke cases in adult patients presenting with stroke-like symptoms.

Interventions
This is an observational study with no interventions. The study methodology involves:
1. Collecting clinical features from suspected stroke patients upon hospital arrival, as documented in ambulance and emergency department records.

2. Blood sample collection:
- Fingerprick capillary blood sample for the LVOne test.
- Venous blood sample (< 4 ml in EDTA tube) for processing and storage.

3. Testing using UpFront Diagnostics' GFAP and D-dimer lateral flow tests (LVOne test), with results available within 15 minutes.

4. Processing of venous blood samples:
- Centrifugation and plasma aliquoting within 4 hours of collection
- Freezing of plasma at -80°C for later analysis

5. Comparing diagnostic results from the LVOne test and biomarker analyses with final diagnoses determined through clinical evaluation and brain imaging (CT and/or MRI).

The study will be conducted at three major stroke centres in Greater Manchester: Salford Royal Hospital, Fairfield General Hospital, and Stepping Hill Hospital. Participants will be followed up prior to hospital discharge to collect information on final diagnosis and treatment.

Intervention Type
Other

Primary outcome(s)
1. Diagnostic accuracy of models for determining intracerebral haemorrhage (ICH) is measured using point-of-care GFAP and D-dimer tests (LVOne test) at baseline and prior to hospital discharge
2. Diagnostic accuracy of models for determining large vessel occlusion (LVO) is measured using point-of-care GFAP and D-dimer tests (LVOne test) at baseline and prior to hospital discharge
3. Final diagnoses of intracerebral haemorrhage (ICH) are measured using CT/MRI prior to hospital discharge
4. Final diagnoses of large vessel occlusion (LVO) are measured using CT/MRI prior to hospital discharge

Key secondary outcome(s))
1. Sensitivity, specificity, positive predictive value, and negative predictive value for identifying intracerebral haemorrhage (ICH) and large vessel occlusion (LVO) are measured using the LVOne test (GFAP and D-dimer levels) compared with final diagnoses determined by brain imaging (CT /MRI) at baseline (on hospital arrival) and prior to hospital discharge
2. Diagnostic accuracy metrics of the developed models compared with those of the Face Arm Speech Test (FAST) and other standard diagnostic tools are measured using a retrospective review of ambulance and hospital patient records at baseline (on hospital arrival) to study completion
3. Evidence of the impact of diagnostic models on clinical decision-making, such as changes in treatment pathways or triage decisions, is measured using a retrospective analysis of clinical pathways and decisions documented in patient notes from baseline (on hospital arrival) to study completion

Completion date
15/12/2026

Eligibility

Key inclusion criteria
1. The patient arrived at the study hospital via emergency ambulance.
2. The patient is 18 years of age or older.
3. Ambulance staff suspected a new acute stroke prior to arrival at the hospital.
4. Stroke symptoms began within 6 hours of sample collection (if the onset was not witnessed, the patient was last known to be well less than 6 hours ago).
5. Blood samples can be collected prior to the administration of any treatment.
6. Urgent brain imaging is planned as part of the patient's diagnostic pathway.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. The patient was assessed at another hospital and transferred for ongoing care.
2. The patient had a recent diagnosis (within the last 4 weeks) of deep vein thrombosis, pulmonary embolism, arterial embolism, stroke, transient ischaemic attack, long bone fracture, major trauma, or surgery under general anaesthesia, as these conditions may increase D-dimer levels.
3. The patient had a recent head injury (within the last 4 weeks) requiring hospital care, as this may increase GFAP levels.
4. Stroke symptoms started more than 6 hours prior to sample collection.

Date of first enrolment
01/10/2025

Date of final enrolment
31/10/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Stockport NHS Foundation Trust
Stepping Hill Hospital
Poplar Grove

Stockport
United Kingdom
SK2 7JE

Study participating centre
Fairfield General Hospital
Fairfield General Hospital
Rochdale Old Road
Bury
United Kingdom
BL9 7TD

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Other

Funder Name
Translation Manchester Accelerator Awards, Confidence for Translation (C4T) 2024 scheme

Funder Name
University of Manchester

Alternative Name(s)
The University of Manchester, University of Manchester UK, University of Manchester in United Kingdom, UoM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon reasonable request from Prof. Adrian Parry-Jones (adrian.parry-jones@manchester.ac.uk).

Details of the data sharing plan:
Type of data to be shared: Anonymised clinical data and biomarker test results collected during the study, including diagnostic model outputs and final diagnosis imaging results.

Data availability: Data will become available after the study results are published and will remain accessible for a minimum of 5 years.

Access criteria: Data will be shared with researchers affiliated with academic or healthcare institutions for the purpose of conducting ethically approved research into stroke diagnosis and management. A data-sharing agreement will be required.

Mechanism: Researchers can request access to the data by contacting the primary investigator. Requests will be reviewed by the study team, and approval will be based on alignment with ethical guidelines and data-sharing agreements.

Consent and anonymisation: All shared data will be fully anonymised, ensuring no participant can be identified. Participant consent has been obtained for the use and sharing of anonymised data.

Ethical and legal restrictions: Data sharing will comply with relevant ethical and legal requirements, including GDPR and the study's ethical approvals. Anonymisation will ensure privacy and data security.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	independent consultee information version 1.0	13/01/2025	29/01/2025	No	No
Participant information sheet	version 1.0	13/01/2025	29/01/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes