

# Evaluation of blood biomarkers for the identification of serious stroke

<b>Submission date</b> 16/03/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 26/04/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/08/2022	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Making a diagnosis of a stroke can be difficult. Some people suffer symptoms that suggest a stroke, but assessments and tests at hospital confirm a different diagnosis such as a migraine or infection. When a stroke does occur, the treatment needed is different depending on the type of stroke. For the most serious type of stroke caused by a blood clot blocking a large artery (called large vessel occlusion stroke [LVO]), an urgent operation improves the chance of recovery. However, this operation is very specialised and only available in certain regional hospitals. Currently, there are no specific tests that can be used in emergency ambulances to help make a confident diagnosis of stroke or to tell which type of treatment may be required. Consequently, patients with LVO stroke typically have to be transferred to a specialised regional hospital after tests that confirm this diagnosis at their local hospital. This results in delays to the emergency operation which can decrease the chance of recovery. This study will investigate whether levels of two natural blood chemicals called d-dimer and purine may help to tell if a person has LVO stroke.

### Who can participate?

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

### What does the study involve?

Participants will have blood tests to measure the levels of two natural blood chemicals called 'd-dimer' and 'purine', and data will be collected about the results of the current routine tests which are conducted to investigate a possible stroke. The d-dimer and purine levels will be compared with the routine tests to determine if these blood levels may be able to assist with making an early diagnosis of stroke.

### What are the possible benefits and risks of participating?

This research is being conducted to determine if the blood levels of d-dimer and purine may be useful for identifying a serious type of 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?  
Northumbria Specialist Emergency Care Hospital (UK)

When is the study starting and how long is it expected to run for?  
October 2021 to December 2024

Who is funding the study?  
Newcastle University (UK)

Who is the main contact?  
Hannah Lumley  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Hannah Lumley

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
308038

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
CPMS 51726, IRAS 308038

## Study information

**Scientific Title**  
Stroke Biomarker Evaluation for Large Vessel Occlusion (StroBE-LVO)

**Acronym**

StroBE-LVO

**Study objectives**

The primary objective is to determine whether blood concentrations of D-dimer (DD) and whole blood purine (WBP) individually or in combination can predict the presence of LVO stroke in patients arriving at hospital with a paramedic assigned diagnosis of suspected acute stroke.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 15/02/2022, 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)207 1048091; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 22/NE/0013

**Study design**

Observational; Design type: 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 determine whether blood concentrations of d-dimer and/or whole blood purine can predict the presence of large vessel occlusion stroke.

Patients arriving at hospital with a paramedic diagnosis of suspected stroke are suitable for inclusion provided that symptoms commenced within 6 hours and blood sampling can be undertaken before any stroke-specific treatments (eg thrombolysis) are administered.

D-dimer will be measured using a standard venous blood sample analysed in the routine hospital laboratory. Purine will be measured from a fingerprick blood sample using a bespoke point of care device.

Following consent to enter the study, routine clinical data required for the study analyses will be collected.

**Intervention Type**

Other

**Primary outcome(s)**

Area under the Receiving Operating Curve (ROC), sensitivity, specificity, negative and positive predictive values for identification of LVO stroke calculated from blood values and reference standard tests

### **Key secondary outcome(s)**

Area under the Receiving Operating Curve (ROC), sensitivity, specificity, negative and positive predictive values for identification of any stroke calculated from blood values and reference standard tests

### **Completion date**

31/12/2024

## **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. At least responsive to tactile stimuli (i.e. A, V or P on the AVPU scale) on hospital arrival
5. New suspected stroke symptoms are still present when taking blood measurements
6. Blood sampling can be undertaken within 6 hours of suspected stroke symptom onset/last known well (times determined by hospital specialist staff)
7. Blood sampling can be undertaken prior to any reperfusion treatments
8. 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

### **Key exclusion criteria**

1. Already assessed at another hospital and ambulance admission is a transfer for continuing care
2. Hypoglycaemia (capillary glucose  $<3.5$  mmol/l)
3. External signs of significant acute trauma which are likely to need additional treatment (large haematomas, open wounds, limb deformity)
4. Assigned a recent previous (within the last 4 weeks) diagnosis likely to have resulted in elevated D-dimer levels i.e. deep vein thrombosis, pulmonary embolism, arterial embolism, stroke, long bone fracture, major trauma, any surgery under general anaesthesia
5. Chemotherapy or radiotherapy treatment for cancer within the last 7 days

**Date of first enrolment**

15/07/2022

**Date of final enrolment**

31/03/2024

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Northumbria Specialist Emergency Care Hospital**

Northumbria Way

Cramlington

United Kingdom

NE23 6NZ

## Sponsor information

**Organisation**

Northumbria Healthcare NHS Foundation Trust

**ROR**

<https://ror.org/01gfeyd95>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Newcastle University

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

## Location

United Kingdom

# 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No