# Evaluation of blood biomarkers for the identification of serious stroke

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| **Submission date**<br>16/03/2022 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered |
| | | [_] Protocol |
| **Registration date**<br>26/04/2022 | **Overall study status**<br>Completed | [_] Statistical analysis plan |
| | | [_] Results |
| **Last Edited**<br>02/08/2022 | **Condition category**<br>Circulatory System | [_] Individual participant data |
| | | [_] 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
hannah.lumley@newcastle.ac.uk

# Contact information

## Type(s)
Scientific

## Contact name
Ms Hannah Lumley

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# Additional identifiers

## EudraCT/CTIS number
Nil known

## IRAS number
308038

## ClinicalTrials.gov number
Nil known

## Secondary identifying numbers
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

## Secondary study design
Cohort study

## Study setting(s)
Hospital

## 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 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 measure
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

## Secondary outcome measures
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

## Overall study start date
01/10/2021

## 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

## Age group
Adult

## Lower age limit
18 Years

## Sex
Both

## Target number of participants
Planned Sample Size: 130; UK Sample Size: 130

## 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
England

United Kingdom

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

# Sponsor information

## Organisation
Northumbria Healthcare NHS Foundation Trust

## Sponsor details
North Tyneside General Hospital
Rake Lane
North Shields
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United Kingdom
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**
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

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

**Intention to publish date**
31/12/2024

**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](HRA research summary)                    28/06/2023       No                    No