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Evaluation of blood biomarkers for the identification of serious stroke

Submission date	**Recruitment status**	[X] Prospectively registered
16/03/2022	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/04/2022	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/08/2022	Circulatory System	[ ] 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

Contact details
Stroke Research Group
Population Health Sciences Institute
The Medical School
Newcastle University
Newcastle upon Tyne
United Kingdom
NE2 4HH
+44 (0)1912085847
Hannah.Lumley@ncl.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
308038

Central Portfolio Management System (CPMS)
51726

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

Primary study design
Observational

Study design
Observational; Design type: Cohort study

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?
HRA research summary			28/06/2023	No	No