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Purines for rapid identification of stroke mimics

Submission date 28/01/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 13/02/2019	**Overall study status** Completed	
Last Edited 13/12/2021	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Currently, without specialist hospital assessments and tests, it can be difficult to tell the difference between a stroke and some other illness that have symptoms like stroke. Other illnesses which have symptoms like stroke are called ‘stroke mimic’ conditions. Examples of stroke mimic conditions are some infections and migraine. The treatments for a stroke and a ‘stroke mimic’ condition are very different. This can be treatment in different hospital departments or even in completely different hospitals. This is because some urgent stroke treatments are only available in very specialised regional hospitals. Because it can be difficult to tell the difference between stroke and stroke mimic conditions, ambulance staff sometimes take people to a less appropriate location initially. This means that some patients have to be transferred between hospital departments or to a second hospital after initial assessments have been conducted at the first hospital a person was taken to. This can result in delays to emergency treatment for patients suffering both types of illness. This study is evaluating a quick and easy new finger prick blood test which may help to rapidly tell the difference between a stroke and a stroke mimic condition. The test is small and portable so that it can be used in ambulances as well as in hospital.

Who can participate?
Patients aged 18 and over with symptoms of suspected stroke

What does the study involve?
Participants undergo the new test and all routine tests which would be conducted to investigate suspected stroke symptoms. The results of the new test are compared with routine tests to determine if this new test is useful. The first finger prick test takes place in the emergency ambulance by staff trained to perform the test. The test involves a finger prick to obtain a sample of blood which is then placed onto a strip (called ‘SMARTChip’). The other end of the strip is placed into a device. The reading is not available to the staff or patients as is typical in this type of study to evaluate a new test. Following arrival at hospital, some of the patients undergo a second finger prick test conducted by trained hospital research support staff or a trained member of the routine clinical team. The second test is done wherever the patient is located on arrival at hospital, most likely the emergency department or the acute stroke unit. Routine clinical data required for the study are collected. There is no study-specific data collection.

What are the possible benefits and risks of participating?
This study is being conducted to see whether a new test may be useful for telling the difference between a stroke and a stroke mimic condition. If the new test works, in the future it could be used as part of routine ambulance assessments to enable staff to make a distinction between stroke and stroke mimic conditions. Patients could be transported immediately to the most appropriate location for care. 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. There should be no disadvantages for individuals taking part in this study and the treatment an individual receives will not change. The new test will involve pricking one or two fingers which may be slightly uncomfortable but should not cause any ongoing irritation or discomfort. If there are any ongoing problems, these will be addressed as part of the patient's routine clinical care. There should be no disadvantages for individuals taking part in this study and the treatment an individual receives will not change.

Where is the study run from?
Participating Hospitals:
1. Northumbria Specialist Emergency Care Hospital (UK)
2. Salford Royal Hospital (UK)
3. Royal Blackburn Hospital (UK)
4. Royal Stoke University Hospital (UK)

Participating Ambulance Services (HQ):
1. North East Ambulance Service NHS Foundation Trust (UK)
2. North West Ambulance Service NHS Trust (UK)
3. West Midlands Ambulance Service NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2018 to March 2021

Who is funding the study?
Innovate UK

Who is the main contact?
1. Dr Anne Oyewole
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
39937

Study information

Scientific Title
Purines for Rapid Identification of Stroke Mimics (PRISM): a diagnostic accuracy study

Acronym
PRISM

Study objectives
This study aims to determine whether a portable point of care purine assay using a finger-prick blood sample can differentiate between stroke and stroke mimic conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)

North East - Newcastle & North Tyneside 1 Research Ethics Committee, NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, Tel: +44 (0)2071048083, Email: nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net, 24/12/2018, ref: 18/NE/0307

Primary study design
Observational

Study design
Observational; Design type: Cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Stroke

Interventions
This research project is an observational cohort study to evaluate whether blood purine levels measured using a new finger prick blood test (called SMARTChip Purine assay) may differentiate between stroke and stroke mimic conditions. The project also involves a sub-study to evaluate whether blood purine levels may also be useful for helping to diagnose a more serious stroke being caused by blockage of a large blood vessel. Participants will undergo either one or two finger prick blood tests, and all routine tests to investigate suspected stroke.

The first finger prick test will be undertaken in the emergency ambulance by staff trained to perform the test. Patients whom ambulance staff consider have suspected stroke symptoms which commenced within 4 hours are suitable to undergo the test provided that they are being conveyed to a hospital taking part in the study. The test involves a finger prick to obtain a sample of blood which is then placed onto a strip containing the purine analysing agents (called 'SMARTChip'). The other end of the strip is placed into a bespoke reader device which stores the data about the purine level. The purine reading will not be available to the staff or patients as is typical in this type of study to evaluate a new diagnostic test.

Following arrival at hospital, some patients will fulfil the additional eligibility criteria for the sub-study (symptom onset within 6 hours, assay can be undertaken before reperfusion treatments). These patients will undergo a second finger prick test at this stage. The second test will be conducted by trained hospital research support staff or a trained member of the routine clinical team. The second test will be done wherever the patient is located on arrival at hospital. Most likely this will be the emergency department or the acute stroke unit.

Following consent to enter the study, routine clinical data required for the study analyses will be collected. There is no study specific data collection.

Reference standard tests: Expert clinical opinion informed by brain imaging and/or other investigations will assign the following reference standard diagnoses at 7 days: ischaemic stroke, haemorrhagic stroke, TIA, stroke mimic conditions.

Index test: Purine measurement data will be harvested from the bespoke purine readers.

Pre-hospital and hospital routinely collected data are required for this study. Ambulance staff will complete a short study specific proforma which they will leave at hospital with the new test equipment (test equipment and hospital interaction described earlier). Hospital research support staff will transcribe routinely available hospital data onto the research paperwork /online database. Copies of some images (e.g. CT scans) are also required for the study and these will be provided to the research team on a CD or in an electronic format as systems allow. All data will be provided to the research team using pseudoanonymised number codes only.

For the majority of participants, hospital research support staff or a trained member of the clinical team will obtain consent on the hospital ward where the patient is located. However, if a participant is discharged before consent can be obtained, a postal invitation letter and consent form will be used.

Intervention Type
Device

Primary outcome(s)
Sensitivity, specificity, negative and positive predictive values, and area under the Receiving Operating Curve (ROC) calculated using purine readings (SMARTChip Purine assay) and results of reference standard tests. Timepoint(s): tests conducted in the emergency ambulance and on arrival at hospital

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/03/2021

Eligibility

Key inclusion criteria
Trained ambulance personnel (paramedics or technicians) responding to an emergency call will attempt a finger prick reading on patients that fulfil the following criteria:

Inclusion criteria:
1. Aged 18 years and over
2. At least responsive to strong stimuli during assessment of conscious level (A, V or P on the AVPU scale)
3. Face Arm Speech Test (FAST) positive or any observed new focal neurological symptoms indicating suspected acute stroke in the ambulance personnel's clinical judgement
4. Persistence of the new stroke-like symptoms during the initial clinical assessment
5. Believed to be within 4 hours of the new stroke-like symptoms at the time of the first clinical assessment
6. Will be transported to a study hospital

In order to provide the population to fulfil the objectives of the substudy, trained hospital staff (when available) will attempt a reading on the following subgroup of patients:
1. Had an assay reading attempted by ambulance personnel (whether successful or not)
2. The symptoms resulting in admission are believed to have commenced within 6 hours of the

time that the hospital assay can be performed
3. The hospital assay can be performed before intravenous thrombolysis or mechanical thrombectomy if this treatment is indicated

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Exclusion criteria for the ambulance finger prick reading are:
1. Hypoglycaemia (capillary glucose < 3.5mmol/l)
2. External signs of significant acute trauma which are likely to need additional treatment (large haematomas, open wounds, limb deformity)
3. Currently receiving chemotherapy or radiotherapy treatment for cancer

Date of first enrolment
01/04/2019

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
United Kingdom

England

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

Study participating centre

Salford Royal Hospital
Stott Ln
Salford
United Kingdom
M6 8HD

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

Study participating centre
Royal Stoke University Hospital
Newcastle Rd
Stoke-on-Trent
United Kingdom
ST4 6QG

Study participating centre
North East Ambulance Service NHS Foundation Trust
Bernicia House
Goldcrest Way
Newburn Riverside
Newcastle upon Tyne
United Kingdom
NE15 8NY

Study participating centre
North West Ambulance Service NHS Trust
Ladybridge Hall Headquarters
Chorley New Road
Bolton
United Kingdom
BL1 5DD

Study participating centre
West Midlands Ambulance Service NHS Foundation Trust
Millennium Point
Waterfront Business Park

Waterfront Way
Brierley Hill
United Kingdom
DY5 1LX

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Government

Funder Name
Innovate UK; Grant Codes: 90169-463228

Alternative Name(s)
Technology Strategy Board

Funding Body Type
Government organisation

Funding Body Subtype
National government

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?
Protocol article		20/05/2021	24/05/2021	Yes	No
HRA research summary			28/06/2023	No	No