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Ambulance feasibility study of a rapid blood test for stroke

Submission date
29/04/2024

Recruitment status
No longer recruiting

Registration date
03/05/2024

Overall study status
Completed

Last Edited
04/06/2024

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Mechanical thrombectomy (MT) is a highly successful treatment for acute ischemic stroke triggered by a blockage in a large blood vessel (large vessel occlusion; LVO). Approximately 15,000 ischaemic strokes are eligible for MT in the UK each year. With the growing technological advances in both arterial imaging and thrombectomy techniques, this number will increase in the future. Due to the proximal site of arterial occlusion in LVO, these strokes tend to cause severe disability or death if untreated. Emergency treatment of LVO by MT reduces the chance of long-term disability and mortality and earlier treatment produces significantly better outcomes and health care savings, but optimising delivery faces many challenges due to:
1. Stroke-like symptoms that mimic LVO can also be due to lacunar stroke from small vessel infarction, intracerebral haemorrhage, transient ischaemic attack (TIA) and non-vascular conditions such as seizures and migraines. Ruling in LVO from such a complex cohort of 'suspected stroke' patients currently requires specialist assessment and brain imaging only performed in-hospital;
2. Less than a third of stroke units are regional MT providers, meaning that many patients are initially taken to their local stroke unit, and then transferred to a thrombectomy centre. This leads to a median treatment delay of 2 hours by the time patients are identified and transferred between sites, with every 1-hour of delay increasing the chance of disability and dependence by 20%.

Currently, no tools are used in the pre-hospital to identify LVO and redirect suspected patients to regional MT providers.Tools to help ambulance clinicians diagnose LVO and transport patients immediately to a thrombectomy centre are vital.

This clinical feasibility study aims at assessing the feasibility of using the LVOne test during ambulance clinical assessment. LVOne is a new finger-prick blood test which is designed to help ambulance clinicians diagnose ischaemic strokes.
The test kit consists of 2 separate blood tests. One of them measures D-dimer. The D-dimer levels are high when a stroke is associated with a blood clot, i.e. ischaemic stroke. The second test measures Glial Fibrillary Acidic Protein (GFAP) which is elevated when patients have

haemorrhagic stroke (i.e. brain bleed). You will receive training and guidance on how to use and interpret the LVOne test.
Prior studies have shown that the LVOne test has 90% accuracy in identifying ischaemic strokes.

The purpose of the RADIOS study is to determine whether the LVOne test can be used by ambulance staff to diagnose patients with ischaemic strokes. If they can, this could see these stroke patients being assessed before arriving at hospital.
However, patients in this study will be assessed and treated in the standard way, and the results of the LVOne test will not be acted upon.
Future studies will explore use of the LVOne test in ambulance setting to reduce treatment times for stroke patients and improve their recovery.

Who can participate?
All patients evaluated by ambulance clinicians for a new acute suspected stroke will be evaluated for study eligibility.

What does the study involve?
The study includes performing the LVOne test, which, from the patient perspective, involves collecting a fingerstick blood sample and testing with the device.

What are the possible benefits and risks of participating?
There are no benefits for the participants and we do not expect any significant risk associated to the test procedure as this study is observational and the intervention involves a fingerstick blood sample which is known to be very safe.

Where is the study run from?
Pockit diagnostics Ltd, T/A Upfront diagnostics (UK)

When is the study starting and how long is it expected to run for?
April 2024 to September 2024

Who is funding the study?
Pockit diagnostics Ltd, T/A Upfront diagnostics (UK)

Who is the main contact?
Dr Edoardo Gaude, edoardo.gaude@pockitdx.co.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Edoardo Gaude

ORCID ID
https://orcid.org/0000-0001-8523-7792

Contact details
University Of Cambridge CRUK
Robinson Way

CAMBRIDGE
United Kingdom
CB2 0RE
+44 1223 363608
edoardo.gaude@pockitdx.co.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
332951

Protocol serial number
REC-292, IRAS 332951

Study information

Scientific Title
Rapid Ambulance DIagnosis Of Stroke (RADIOS): a pre-hospital feasibility study

Acronym
RADIOS

Study objectives
Ambulance clinicians find the LVOne test feasible to use during ambulance assessment.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 07/05/2024, Cambridge Central Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 207 1048098; cambridgecentral.rec@hra.nhs.uk), ref: 23/EE/0226

Study design
Prospective feasibility cohort study

Primary study design
Observational

Study type(s)
Diagnostic, Other

Health condition(s) or problem(s) studied
Suspected stroke

Interventions

The intervention associated to this study is performing the LVOne test, which, from the patient perspective, involves collecting a fingerstick blood sample and testing with the device. The total observation is limited to the duration of in-hospital stay and there is no follow-up.

The LVOne test consists of two portable lateral flow assays: assay 1 measures blood D-dimer concentration and assay 2 measures blood GFAP concentration (Upfront diagnostics). The main analysis will include ambulance clinicians' opinions on the feasibility of the LVOne test during routine ambulance visits for the pre-hospital evaluation of LVO stroke.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
LVOne

Primary outcome(s)
Expert opinions on the feasibility of the LVOne test during routine ambulance visits. The method used to collect this data is qualitative evaluation in the form of a questionnaire.

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

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. Attended by study trained ambulance clinician
2. Evaluated for suspected acute stroke
3. Within 6 hours of symptom onset
4. Age >18 years
5. Local hospital is Cambridge University Hospital (or other thrombectomy-capable hospital)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit

99 years

Sex
All

Key exclusion criteria
1. Witnessed seizure at presentation
2. Hypoglycaemia, (blood glucose <3mmol/l)
3. Severe frailty or limited life expectancy <6 months
4. Patient is not conveyed to Cambridge University Hospital (or other thrombectomy-capable hospital)

Date of first enrolment
01/07/2024

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
East of England Ambulance Service NHS Trust
Unit 3
Whiting Way
Melbourn
Royston
United Kingdom
SG8 6NA

Sponsor information

Organisation
Pockit diagnostics Ltd, T/A Upfront diagnostics

Funder(s)

Funder type
Industry

Funder Name
Pockit diagnostics Ltd, T/A Upfront diagnostics

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Edoardo Gaude, edoardo@upfrontdiagnostics.com

IPD sharing plan summary
Available on request