

# Ambulance feasibility study of a rapid blood test for stroke

<b>Submission date</b> 29/04/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 03/05/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 04/06/2024	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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**

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## Additional identifiers

**Integrated Research Application System (IRAS)**  
332951

**Protocol serial number**  
REC-292

## 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](mailto:edoardo@upfrontdiagnostics.com)

## IPD sharing plan summary

Available on request