

# Identifying a blood test to predict risk of deterioration of brain haemorrhage

<b>Submission date</b>	<b>Recruitment status</b>	<input checked="" type="checkbox"/> Prospectively registered
04/02/2015	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
13/02/2015	Completed	<input type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
04/09/2017	Circulatory System	<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Stroke is a serious, life-threatening medical condition that usually happens when a blood clot or haemorrhage cuts off the blood supply to an area of the brain. One in 5 strokes, is caused by a haemorrhage (intracerebral haemorrhage (ICH)). A high number of patients who have a ICH die within the first few hours and more than half of those who do survive are left with a long term disability. In around a third of cases the brain tissue becomes swollen and inflamed around the blood clot (haematoma) in the hours after the initial bleed into the brain. This is known as haematoma expansion and means it has grown in size. As the space within the skull is already tight, any swelling puts huge pressure of the brain itself, squashing it and causing brain damage. A patient who initially appeared to be quite well can suddenly deteriorate and lose consciousness, often requiring emergency surgery to relieve the pressure within the brain. Finding a treatment to prevent haematoma expansion has proven difficult as by the time the symptoms present, it may be too late to show any real benefit. Whilst it is important to establish which patients are most at risk of haematoma expansion, current tests using signs on brain imaging have proved less than reliable, so this remains a target for researchers. The aim of this study is to identify a blood test that will detect novel biomarkers (which can be defined as "medical signs" that can help predict a disease or outcome of a disease) that predict early haematoma expansion after intracerebral haemorrhage.

### Who can participate?

Adults that have had a ICH, are likely to survive beyond the next 24 hours and from which a blood sample can be taken within 3 hours of the ICH.

### What does the study involve?

Blood samples are taken from each participant within 3 hours of onset of symptoms of intracerebral haemorrhage for proteomic (protein) analysis of novel biomarkers. They also have a CT scan (brain imaging) 24-36 hours after their ICH to look for signs of a haematoma expansion. Plasma biomarkers of patients with and without haematoma expansion are compared.

### What are the possible benefits and risks of participating?

There are no benefits to study participation as this is an observational study. Risks are

associated with blood sampling (bruising) and exposure to radiation when undergoing CT scan (equivalent to half the yearly background radiation).

Where is the study run from?

Salford Royal NHS Foundation Trust (UK)

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

April 2015 to December 2018

Who is funding the study?

Salford Royal NHS Foundation Trust Hyperacute Research fund (UK)

Who is the main contact?

Dr Adrian Parry-Jones

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Adrian Parry-Jones

### Contact details

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## Additional identifiers

### Protocol serial number

V1; 9/2/15

## Study information

### Scientific Title

Identification of novel biomarkers to predict early haematoma expansion after intracerebral haemorrhage

### Acronym

PRIME-ICH

## **Study objectives**

The aim of this study is to identify a blood test that will detect novel biomarkers that predict early haematoma expansion after intracerebral haemorrhage.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

North West - Haydock Research Ethics Committee, 28/05/2016, ref: 15/NW/0387

## **Study design**

Prospective cohort study

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic

## **Health condition(s) or problem(s) studied**

Intracerebral haemorrhage (haemorrhagic stroke)

## **Interventions**

Blood sampling within 3 hours of onset of symptoms of intracerebral haemorrhage for proteomic analysis of novel biomarkers. Research brain imaging (CT scan) at 24-36 hour from symptoms onset for signs of haematoma expansion. Plasma biomarkers of patients with and without haematoma expansion will be compared.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

Identification of novel biomarkers for risk of early haematoma expansion after ICH and identification of a proteomic profile of plasma in hyperacute ICH patients who progress to haematoma expansion. This will be measured by analysis inflammatory biomarkers and proteomic profile of the baseline blood sample (taken within 3 hours of symptom onset).

## **Key secondary outcome(s)**

N/A

## **Completion date**

31/12/2018

## **Eligibility**

### **Key inclusion criteria**

1. Diagnosis of primary ICH confirmed by CT brain scan
2. Ability to collect research blood sample within 3 h of symptom onset
3. Likely to survive beyond 24 h (e.g. GCS > 5)

4. ICH not felt to be secondary to an underling structural abnormality (vascular malformation, aneurysm, tumour) or trauma.

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Under 18
2. End of life (not expected to survive passed 24 h)
3. Other concomitant condition
4. Participation in a CTIMP
5. Pregnancy

**Date of first enrolment**

01/05/2015

**Date of final enrolment**

31/12/2017

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

Salford Royal NHS Foundation Trust

Stott Lane

Salford

United Kingdom

M6 8HD

## Sponsor information

**Organisation**

University of Manchester

**ROR**

<https://ror.org/027m9bs27>

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Salford Royal NHS Foundation Trust Hyperacute Research fund (UK)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No