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

**Submission date**
04/02/2015

**Recruitment status**
No longer recruiting

**Registration date**
13/02/2015

**Overall study status**
Completed

**Last Edited**
04/09/2017

**Condition category**
Circulatory System

[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
Stroke is a serious, life-threatening medical condition that usually happens when a blood clot or haemorrhage cuts of 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

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
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

## Secondary study design
Cohort study

## Study setting(s)
Hospital

## Study type(s)
Diagnostic

## Participant information sheet

## 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 measure

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).

### Secondary outcome measures
N/A

### Overall study start date
01/04/2015

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
40

### 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
England

United Kingdom

### Study participating centre
**Salford Royal NHS Foundation Trust**
Stott Lane
Salford
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M6 8HD

## Sponsor information

### Organisation
University of Manchester

### Sponsor details
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### Sponsor type
University/education

### Website
FMHS Research Governance Website

### 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

## Publication and dissemination plan

## Intention to publish date

## 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? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |