

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

Submission date 04/02/2015	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 13/02/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 04/09/2017	Condition category Circulatory System	☐ 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 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 on 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

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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

Primary study design

Observational

Study design

Prospective cohort study

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 underlying 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?
HRA research summary			28/06/2023	No	No