PROHIBIT-ICH
Prevention Of Hypertensive Injury to the Brain by Intensive Treatment in IntraCerebral Haemorrhage

SITE INTIATION VISIT
<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Email</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chief Investigator</td>
<td>Professor David Werring</td>
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<td></td>
</tr>
<tr>
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<tr>
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<tr>
<td>(BP Monitoring Centre)</td>
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<td>Tel: 01865 234622</td>
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<tr>
<td>(BP Monitoring Centre)</td>
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<tr>
<td>BP Clinical Research Fellow:</td>
<td>Iain McGurgan</td>
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<td>Tel: 01865 231601</td>
</tr>
<tr>
<td>(BP Monitoring Centre)</td>
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### List of Sites

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Site</th>
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</thead>
<tbody>
<tr>
<td>Professor David Werring</td>
<td>University College Hospital, London</td>
</tr>
<tr>
<td>Professor Peter Rothwell</td>
<td>John Radcliffe Hospital, Oxford</td>
</tr>
<tr>
<td>Dr Soma Banerjee</td>
<td>Charing Cross Hospital, London</td>
</tr>
<tr>
<td>Professor Rustam Al-Shahi Salman</td>
<td>Royal Infirmary of Edinburgh</td>
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<tr>
<td>Dr Adrian Parry-Jones</td>
<td>Salford Royal Hospital, Manchester</td>
</tr>
<tr>
<td>Prof Hedley Emsley</td>
<td>Royal Preston Hospital</td>
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<td>Dr Dulka Manawadu</td>
<td>Kings College Hospital, London</td>
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<td>Dr Niamh Hannon</td>
<td>Addenbrooke's Hospital, Cambridge</td>
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<td>Dr Kailash Krishnan</td>
<td>Nottingham University Hospitals NHS Trust</td>
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<tr>
<td>Dr Keith Muir</td>
<td>Queen Elizabeth University Hospital, Glasgow</td>
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<tr>
<td>Dr Liqun Zhang</td>
<td>St George’s Hospital, London</td>
</tr>
<tr>
<td>Dr Kirsty Harkness</td>
<td>Sheffield Teaching Hospitals NHS Foundation Trust</td>
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</tbody>
</table>
AGENDA

1. Introduction to the Study and Scientific Background

2. Study protocol
   - Objectives
   - Primary and secondary outcomes
   - Inclusion and exclusion criteria

3. Trial Co-ordination from Oxford
   - Blood Pressure Device
   - Prescription Change

4. Trial Co-ordination from UCL
   - Clinical Data collection/Follow-up
   - Questionnaires and assessments
   - MRI Protocol
Introduction to the Study and Scientific Background
Importance of intracerebral haemorrhage

• About 10-20% of all strokes worldwide\(^1\)
• Median 1 month case fatality 40%\(^2\)
• ~ 60%-90% of survivors survivors are dependent\(^2\)
• Case fatality not improved 1980-2006\(^2\)
• Incidence not declining in elderly populations despite better BP control\(^3\)
  • especially antithrombotic related
  • ? related to CAA
• Few effective treatments

1. Lancet Neurol 2009;8:355-69
2. Lancet Neurol 2010;9:167-76
Causes of spontaneous ICH

- Hypertensive arteriopathy
- Cerebral amyloid angiopathy

“primary” ~80%
other causes ~20%

- Arteriovenous malformation
- Aneurysm
- Cavernoma
- AV fistula

- Venous sinus thrombosis
- Clotting problems
- Tumour
- RCVS
- Vasculitis
- Endocarditis

Also see SMASH-U (Structural lesion, Medication, Amyloid angiopathy, Systemic/other disease, Hypertension, Undetermined) for one suggested ICH classification scheme Stroke. 2012;43:2592-2597
A definition of cerebral small vessel disease

A group of pathologies affecting small perforating cerebral arterioles, capillaries (and venules), associated with a characteristic spectrum of clinical and imaging findings

small vessel networks of the brain

cortical-leptomeningeal arterioles and arteries

depth perforators (white matter)

depth perforators (basal ganglia)

Arteriolosclerosis

CAA

Salamon, 1973
## STRIVE: Standards for Reporting and Imaging of Small Vessel Disease

**Lancet Neurol. 2013 Aug;12(8):822-38.**

<table>
<thead>
<tr>
<th></th>
<th>Recent small subcortical infarct</th>
<th>White matter hyperintensity</th>
<th>Lacune</th>
<th>Perivascular space</th>
<th>Cerebral microbleeds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Example image</td>
<td><img src="image1" alt="Example image" /></td>
<td><img src="image2" alt="Example image" /></td>
<td><img src="image3" alt="Example image" /></td>
<td><img src="image4" alt="Example image" /></td>
<td><img src="image5" alt="Example image" /></td>
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<tr>
<td>Schematic</td>
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<td><img src="image7" alt="Schematic" /></td>
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<td><img src="image10" alt="Schematic" /></td>
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<tr>
<td><strong>DWI</strong></td>
<td><img src="image11" alt="DWI" /></td>
<td><img src="image12" alt="DWI" /></td>
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<td><img src="image15" alt="DWI" /></td>
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<tr>
<td><strong>FLAIR</strong></td>
<td><img src="image16" alt="FLAIR" /></td>
<td><img src="image17" alt="FLAIR" /></td>
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<td><img src="image19" alt="FLAIR" /></td>
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<tr>
<td><strong>T2</strong></td>
<td><img src="image21" alt="T2" /></td>
<td><img src="image22" alt="T2" /></td>
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<td><img src="image24" alt="T2" /></td>
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<tr>
<td><strong>T1/FLAIR</strong></td>
<td><img src="image26" alt="T1/FLAIR" /></td>
<td><img src="image27" alt="T1/FLAIR" /></td>
<td><img src="image28" alt="T1/FLAIR" /></td>
<td><img src="image29" alt="T1/FLAIR" /></td>
<td><img src="image30" alt="T1/FLAIR" /></td>
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<tr>
<td><em><em>T2</em>/SWI</em>*</td>
<td><img src="image31" alt="T2*/SWI" /></td>
<td><img src="image32" alt="T2*/SWI" /></td>
<td><img src="image33" alt="T2*/SWI" /></td>
<td><img src="image34" alt="T2*/SWI" /></td>
<td><img src="image35" alt="T2*/SWI" /></td>
</tr>
</tbody>
</table>

| **Usual diameter**   | ≤ 20 mm                         | variable                   | 3-15 mm                   | ≤ 2 mm                  | ≤ 10 mm               |
| **Comment**          | best identified on DWI          | located in white matter    | usually have hyperintense rim | usually linear without hyperintense rim | detected on GRE seq., round or ovoid, blooming |
| **DWI**              | ↑                                | ←                           | ←/↓                       | ←                        | ←                    |
| **FLAIR**            | ↑                                | ↑                            | ↓                         | ←                        | ←                    |
| **T2**               | ↑                                | ↑                            | ↑                         | ↑                        | ←                    |
| **T1**               | ↓                                | ←/↓                         | ↓                         | ↓                        | ←                    |
| **T2*/GRE**          | ←/↑                              | ↑                            | ←/↑                       | ←                        | ↓↓                   |

(↓ if haemorrhage)
Why use an SVD imaging biomarker?

• Can classify the underlying SVD causing ICH
• Reflect brain injury relevant to the adverse consequences of SVD, including cognitive impairment
• Evolve over time so can monitor progression
• A surrogate outcome marker is attractive for a clinical trial, because it may be possible to assess beneficial or hazardous effects of an intervention in a much small number of participants in comparison to clinical event outcomes (e.g. recurrent stroke).
The ideal biomarker for clinical studies

• Clinically meaningful
• Closely representative of the disease’s underlying biological progression
• Efficient at detecting changes in response to treatment
• Reliably and reproducibly measurable
• Easily generalisable across many trial sites.

The development of new CMBs was strongly related to baseline systolic BP (OR 1.28 per unit increase, 95%CI 1.23-1.33, p<0.001). Stroke. 2010 Jan;41(1):184-6.
White matter hyperintensities

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Follow-up</th>
<th>WMH progression</th>
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<tbody>
<tr>
<td>Volumetry, ml</td>
<td>24.6 (27.9)</td>
<td>29.2 (30.5)</td>
<td>4.6 (5.1)**</td>
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<tr>
<td>Fazekas Scale</td>
<td>4.3 (1.4)</td>
<td>4.6 (1.3)</td>
<td>0.3 (0.4)*</td>
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<tr>
<td>ARWMC Scale</td>
<td>12.3 (5.5)</td>
<td>13.2 (5.2)</td>
<td>0.9 (1.5)*</td>
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<tr>
<td>Scheltens Scale</td>
<td>22.7 (8.2)</td>
<td>24.1 (8.0)</td>
<td>1.4 (2.0)**</td>
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<tr>
<td>Schmidt Progression Scale</td>
<td>–</td>
<td>–</td>
<td>0.9 (0.6)***</td>
</tr>
<tr>
<td>Rotterdam Progression Scale</td>
<td>–</td>
<td>–</td>
<td>2.9 (2.9)***</td>
</tr>
</tbody>
</table>
WMH volume increases over time

- Shown in older community and hospital stroke populations
- 26 patients (mean age 69.1) with probable or possible Cerebral Amyloid Angiopathy scanned over ~1yr found median WMH growth of 0.5 mL per year (IQR 0.1-2.8 mL per year)
- 192 participants in the PROGRESS trial mean total new WMH volume was significantly reduced in the active treatment group (0.4 mm$^3$ [SE=0.8]) compared with placebo group (2.0 mm$^3$ [SE=0.7]; P=0.012)
- With 56 patients in each arm we can detect a similar difference in new WMH lesion volume (2.0mm$^3$ vs 0.4mm$^3$) (if the SD does not exceed 2.0 mm$^3$) to that shown overall in PROGRESS, with power 80% at α significance level of P=0.05.

References
Blood pressure in acute stroke
Oxford Vascular Study

Major ischaemic stroke

Maximum post event SBP within 3 hours of stroke onset
Maximum premorbid SBP

Lancet Neurol 2014; 13: 374-84
Telemetric Bluetooth Home Monitoring
COMMIT Study – OXVASC home monitoring

- 1200 patients; 2886 drug changes; 92% uptake

Blood pressure (mmHg)
Conclusions

• Telemetric home BP monitoring is feasible and well tolerated by patients with TIA and non-disabling stroke, irrespective of age, and is found to be helpful by GPs

• Monitoring detects high levels of masked hypertension, and informs titration of medication in the majority of patients

• Monitoring is associated with good BP-control and excellent longer-term compliance with medication

• Intensive BP-lowering titrated according to HBPM is reasonably safe in an elderly population prone to falls

• Residual hypertension detected on home-monitoring is of more prognostic value than on ABPM

• BUT - can it be rolled out across multiple centres?
Study Objectives

Primary Objectives

i). BP study:

Does the use of centralised telemetric home BP monitoring in patients with spontaneous (non-traumatic) ICH achieve a reduction in 3-month BP compared with standard care?

ii). Imaging study:

Does intensive BP treatment using centralised telemetric home monitoring result in a reduction in progression of SVD-related brain injury assessed on MRI compared with standard care?

Including, but not limited to:
- White matter hyperintensities (WMH),
- White matter structural integrity,
- Incident cerebral microbleeds (CMBs),
- Brain atrophy
Study Objectives

Secondary Objectives

i). BP study:

1. Is it feasible in a multi-site setting?
2. Is it safe to intensively lower BP for an extended period of time following spontaneous ICH?
3. Is the intervention acceptable to participants?

ii). Imaging study:

1. Does any reduction in recurrent vascular events (including ICH) or progression of cognitive decline on intensive BP treatment correlate with baseline measures of changes in quantitative and structural brain scan markers of small blood vessel health?
2. Are there any adverse effects on neuroimaging measures (e.g. increased white matter ischaemic injury) associated with intensive BP treatment?
Study Outcomes

Primary Outcomes

i). BP study:
1. **Efficacy**: the magnitude of difference in BP at 3 months in the intervention arm versus control arm
2. **Feasibility**: consent rate; dropout rate from the intervention prior to 1 month; patient approval of the monitoring process
3. **Safety**: serious adverse events related to reducing BP in intervention arm

ii). Imaging study
1. **Efficacy**: the progression in MRI white matter hyperintensity (WMH) volume over 1 year
Study Outcomes

Secondary Outcomes

i). BP study:
Clinical outcomes including recurrent vascular events and cognition; number of BP lowering drugs at 3 months and at 1 year follow-up visits; mean daytime BP at 1 year on 24-hour ABPM

ii). Imaging study:
Neuroimaging outcomes including (but not limited to)
- the proportion of patients who develop new cerebral microbleeds (CMBs) over 1 year
- number of new CMBs at 1 year
- new infarcts or intracerebral haemorrhages at 1 year change in mean diffusivity (MD), fractional anisotropy (FA) and other 3T DTI metrics
- change in cerebral blood flow (CBF) on 3T PCASL
- change in total brain volume, white matter volume and grey matter volume on 3T T1 volumetric images
- composite neuroimaging measures (e.g summary SVD scores)
Recruitment

- Eligible patients will be identified by clinical staff from acute stroke units or high dependency units at participating hospitals, outpatient clinics (stroke, neurology, geriatric, neurosurgical) and from primary care centres.
- Potentially eligible participants will be handed an information leaflet and a letter of invitation.
- Patients will have at least 24 hours to consider the information before being telephoned or approached by a member of research/clinical team at the NHS site to see if they are interested in taking part in the trial.
- If they are, a convenient time will be arranged for them to meet a research staff member delegated by the CI to discuss the study, go through the information sheet, assess eligibility and answer any questions they may have.
Inclusion Criteria

1. Adults (≥40 years) with spontaneous primary ICH
2. BP control since the ICH is deemed not adequate AND the measured SBP prior to randomisation is ≥130 mm Hg
3. Recruitment soon after ICH in encouraged
4. Plan for home discharge (not to a nursing or care home)
5. Can undertake home BP measurements
6. Can complete an MRI scan
7. Can attend and complete the study assessments including cognitive screen
8. Can provide informed consent (or suitable consultee available)
Exclusion Criteria

1. Inability to provide informed consent and lack of suitable consultee
2. Evidence of a macrovascular or structural cause for ICH (e.g. AVM or tumour)
3. Diagnosis of dementia
4. Low Functional status (MRS ≥4) before or after ICH
5. Life expectancy <2 years
6. Taking more than 3 or more BP-lowering medications
7. Consistently good BP control (below 130/80 mm Hg), judged not to require more intensive treatment
8. Flow-restricting intracranial/extracranial large arterial stenosis
9. Contraindication to MRI
10. Absence of mobile phone coverage

• Contra-indication to BP treatments (e.g. symptomatic postural hypotension) is not an absolute exclusion criterion, but more information must be provided
• Note that participation in other CTIMP or device trial is NOT an automatic exclusion criterion
**Basic trial structure**

- **Randomisation**
  - **Intervention**
    - Telemetric Bluetooth home BP monitors will be provided to participants during their inpatient stay or clinic visit, and will commence 3-times-daily readings immediately. The BP monitoring team will assess BP readings daily and advise medication adjustments to achieve a target BP of <120/80 mm Hg
  - **3 month follow-up** (24-hour ABPM, modified MOCA, EQ-5D, BP questionnaire)
  - **12 month follow-up** (MRI scan, 24-hour ABPM, modified MOCA, EQ-5D)

- **Comparator**
  - Standard clinical care including usual BP treatment, without home monitoring, undertaken in the clinical care setting

**Analysis**
Randomisation Procedure

- Patients will be randomised in a 1:1 group assignment ratio to intensive BP lowering (intervention group) or standard care (control group) using an online randomisation service (Sealed Envelope)
- Baseline data collected (as described later)
Blood Pressure Monitoring
BP Measurement at Baseline

- 3 BP measurements (2 seated and one standing after a minimum of 3 minutes)
- The initial measurement should be taken in both arms; if there is a significant difference (>20 mm Hg systolic) between them then the arm with the higher value should be used for subsequent monitoring
- Baseline 24-hour ABPM will be fitted and recorded in all participants
Telemetric Home BP Monitor
BP Treatment/Prescription changes

- The Oxford centre will directly advise patients on starting or adjusting BP medication.
- 1st line treatment will usually be either combination therapy with perindopril and indapamide, or amlodipine 5mg daily.
- Subsequent options will be likely to include the addition of spironolactone, an alpha-blocker and/or a beta-blocker.
- The Oxford BP team will contact the patient directly to advise them on medication changes.
- Changes will be notified to the GP and local research team.
- The GP will provide prescriptions to patients.
BP Target

- <120/80 mm Hg
- If this is consistently achieved, monitors will be collected after a minimum of 1 month
- We expect most will be controlled by 3 months
- 3 month 24-hour ABPM
- Conventional monitors will be issued (weekly readings)
Trial Coordination from UCL

Shahena Butt
Coordination of PROHIBIT-ICH

- Clinical data collection
- Follow-up
- Questionnaires/Assessments
- MRI imaging
- MRI imaging upload and transfer
Clinical Data Collection: eCRF

- Data collection
- Baseline
- 3 month follow-up
- 12 month follow-up
<table>
<thead>
<tr>
<th>Visit No:</th>
<th>Screening</th>
<th>Intervention phase and Follow-ups</th>
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<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>3 Month follow-up</td>
</tr>
<tr>
<td>Visit No:</td>
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<td>2</td>
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<tr>
<td>Informed Consent</td>
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<td></td>
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<td>Medical History</td>
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<td></td>
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<tr>
<td>Eligibility confirmation</td>
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<td></td>
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<tr>
<td>Blood test</td>
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<td></td>
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<tr>
<td>MRI Scan (before randomisation)</td>
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<tr>
<td>Blood Pressure</td>
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<td>X</td>
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<tr>
<td>24-hour ABPM</td>
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<td>X</td>
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<td>Cognitive assessment</td>
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<td>Quality of life assessment (EQ-5D)</td>
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<td>Randomisation</td>
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Clinical Data Collection: eCRF

Data collection

- Electronically on sealed envelope
- Secure, authorised access

PART A: PATIENT ELIGIBILITY

**INCLUSION CRITERIA:**

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<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>Is the patient 40 years old or above?</td>
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<tr>
<td>Does the patient have spontaneous primary ICH? (i.e. without known underlying structural or macrovascular cause)</td>
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<tr>
<td>The patient’s SBP &gt; 140 mm Hg at the time of randomisation?</td>
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<tr>
<td>Is the patient planned for home discharge (not including nursing/care home) after their inpatient stay?</td>
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<tr>
<td>Is the patient willing (and demonstrate ability to) undertake home BP measurements, either unassisted or with the help of a relative, friend or carer?</td>
<td></td>
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</tr>
<tr>
<td>Is the patient able and willing to complete an MRI scan?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the patient able and willing to attend and complete study assessments including cognitive screen?</td>
<td></td>
<td></td>
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<tr>
<td>Is the patient able and willing to provide informed consent?</td>
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</table>

If any of the above are checked “No”, the patient is **NOT eligible** for the study - STOP

**EXCLUSION CRITERIA:**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is there evidence of a macrovascular or structural cause for ICH (e.g. AVM or tumour)?</td>
<td></td>
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</tbody>
</table>
Clinical Data Collection: eCRF

Baseline

- Medical history
- Blood pressure medication
- 3 BP measurements
- 24-hour ABPM
- Blood test (venepuncture)
- MRI brain scan - performed prior to randomisation.
- Cognitive functional assessment (modified Montreal Cognitive Assessment)
- Completion of the EQ-5D questionnaire
Blood Sample - Baseline

- About 5-10mls Blood will be taken from consenting patients
- EDTA blood sampling tube
- Stored at UCL Institute of Neurology, Queen Square for future genetic research.
- Sent in a Safebox from the sites to Shahena
- Royal Mail Safe Boxes will be provided
Clinical Data Collection: eCRF

- **3 month follow-up**
  - 3 month follow-up eCRF
  - BP recorded
  - modified Montreal Cognitive assessment
  - EQ-5D questionnaire
  - home blood pressure acceptability questionnaire
  - 24-hour ABPM

- **12 month follow-up**
  - 12 month follow-up eCRF
  - As Above (minus: home blood pressure acceptability questionnaire)
  - MRI Scan
Questionnaires/Assessments

- Cognitive Assessment

- EQ-5D
  - Standardised instrument for use as a measure of health outcome
  - Two pages
  - EQ-5D descriptive system
  - EQ visual analogue scale
MRI

- Outcomes
- MRI Protocol
- Sequences
- MRI imaging upload and transfer
MRI

**Outcomes**

- change in white matter hyperintensity volume
- change in white matter microstructure (DTI)
- change in the number of CMBs
- change in cerebral atrophy
MRI

- MRI Protocol and Manual
  - For major MRI scanner manufacturer (Siemens, GE Philips)
  - Manual: how to upload a scan
MRI protocol

- **Sequences**
  1. 3D T1 (5min)
  2. 3D FLAIR (5min)
  3. DTI (simplified) (5min)
  4. 3D SWI (5min)
  5. Axial T2 (2min)

- **Optional:** Arterial Spin labelling (5min)

  Total: 27min
MRI Image upload and transfer

- **Set-up: Password protected Log-in**
  1. Name of person uploading the scans
  2. Email address

**Image file requirement:**
- File needs to be compressed – Zip file
MRI Image upload and transfer

http://qsmscentre.org.uk
MRI Image upload and transfer

Queen Square MS Centre - Trials Office Scan Uploader

Upload files
My uploads
Logout
MRI Image upload and transfer

Upload scans

Upload type
- Patient
- Dummy

Site
- PROHIBIT 00

Subject number

Birth Date
- dd/mm/yyyy

Scan
Scan Date
- dd/mm/yyyy

Visit
- Baseline

Comments
MRI Image upload and transfer

Select files

Select Files

No files selected

0 files selected

Start upload Cancel upload

ZIP FILE
MRI Image upload and transfer

Queen Square MS Centre - Trials Office Scan Uploader

1 file(s) uploaded

Upload files
My uploads
Admin
Logout
Where Are We?

• Regulatory:
  - Ethical Approval
  - Final local R&D approval needed

• Operational:
  - Contact made with all sites
  - Gathering local study documentation
  - Creating local Site Files

• Site Initiation:
  - Study team
If All Is In Place...

- LET’S GET STARTED!
- Dissemination via email
- All local study staff members will be included in the email
- Co-ordinator will action
PROHIBIT-ICH
Prevention Of Hypertensive Injury to the Brain by Intensive Treatment in IntraCerebral Haemorrhage

THANK YOU