**PROHIBIT-ICH QUESTIONS**

1. **Access to Sealed Envelope** <https://www.sealedenvelope.com/redpill/prohibit/>

Please check you have access to Sealed Envelope to enter data and randomise participants.

1. **Consent forms**

Please allow at least 24 hours between providing the patient information sheet and obtaining consent. Consent forms are returned to Shahena at UCL please.

There is no maximum time frame from consent to randomisation, so it can be done around clinical care needed, but we would encourage that scans be expedited where possible so that this time is as short as possible.

All other baseline procedures (such as bloods and the 24-hour ABPM fitting etc.) can be performed prior to randomisation so that as soon as the scan is performed we can start the intervention, should the participant be randomised to that group.

1. **3T MRI**

All MRI details can be found in the PROHIBIT-ICH Imaging Manual and please make sure to follow the extra comments below:

1. Interpolation should be off for the 3D scans (T1 and FLAIR) but can be on for the T2
2. Prescan normalize should be turned **on** for all the scans
3. DTI: please make sure the top of the brain is covered; even if the cerebellum is missed. The main part of the brain must be covered.

Any other imaging related queries please email Shahena.butt@ucl.ac.uk at UCL please.

Which MRI web browser is mentioned on page 16 of the manual: **“We recommend you use web browser: Chrome, Firefox or Microsoft Edge. Internet Explorer 6 and 7 are NOT compatible!”**

1. **Baseline assessment**

Can be split across 2 visits as long as

1. The participant is happy with this arrangement
2. The MRI is completed before randomisation

BP measurements required on the e-CRF are for non-dominant arm unless there is a difference >20mmHg systolic between the 2 sides. 3 BP measurements are taken for the eCRF (2 seated and one standing after a minimum of 3 minutes). 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.

Please be prompt filling out the patient information on the e-CRF. The information on baseline medications etc. is needed to recommend medication changes in those in the intervention group.

1. **24 hour BP**

The 24-hour ABPM inflates 7am-11pm, every 30 minutes and in the night time 11pm -7am, every hour. The kit will not display the readings taken throughout the 24 hour. This is how the equipment is set up, not specific to trial protocol.

It is needed for randomisation and analysis. Fitted at baseline, 3 month and 1 year follow up, regardless of group allocation, each need 21 readings to be valid. The 24 hour ABPM is intended to be performed prior to randomisation, but we appreciate that in some cases it makes more sense logistically to send them home with the 24-hour fitted after having randomised, rather than bringing them back to provide the telemetric kit if they are allocated to the intervention arm. On that basis, it is ok to start the 24-hour ABPM the following day, but no later than that if possible.

Those in the control arm won't receive details about their ABPM, unless the mean daytime reading is sufficiently different from their baseline recorded BP (in which case we will contact them and/or their GP on the basis of clinical need).

Please return any kits that need re-programming (E00), and see the TM2430 manual on PROHIBIT Website for other error messages. Please do use the red button to alter any of the program settings.

Please remove batteries for posting 24 hour BP kits, as required by Royal Mail. The rechargeable batteries supplied by the manufacturer do not need to be returned. The device can just be issued with the AA batteries we sent, and disposed of by the participant when the device is posted back.

After seeing a participant and fitting a 24 hour (ambulatory) monitor, please issue one pre-paid jiffy bags, one cardboard wrap, and a sheet of postage instructions to the participant. The instructions explain how after they complete monitoring and remove the 24 hour monitor, they should remove the batteries (as these cannot be posted). The monitor and patient diary are folded into the cardboard wrap, and then placed into the prepaid envelope for return to us. We can return them to you once downloaded by the same mechanism, or by next day courier if further equipment is required by your team.

There have been some participants who have not wanted to start monitoring until they reach home e.g. due to driving. In such cases, please try to fit equipment before they leave. Demonstrate how to turn monitor on and off and ask them to start their 24 hours when they reach their destination.

1. **Bluetooth**

If randomised to intervention, please complete the 24 hour BP prior to starting daily home readings on the Bluetooth kit. They will be using both the monitor and hub during intensive (daily) monitoring. Once they have finished intensive monitoring, they can measure their blood pressure once a week and we have provided paperwork for them to write the readings down (available on the website). There is no rush for them to return the hub to us, so they could keep it (unplugged) and return it to your site at the 12 month follow up. We could then arrange for courier collection from you.

If the patient is away it is much better if they take the BP monitor with them, leaving the hub at home. This allows them to continue to check their BP while away and when they return it automatically uploads all the readings that they performed when on holiday (these will be automatically stored on the device and transferred when the monitor reconnects with the hub when they get back). This will allow us to recommend treatment changes as soon as possible on their return so is certainly preferable from a treatment point of view. It is ok to not record for a few days if the patient is on holidays, and this does not need to be recorded as a protocol violation.

**Please supply the Patient contact details and Loan form to the Oxford Monitoring Team as soon as possible after issuing a Bluetooth kit to anyone randomised to intervention using our secure email address** [**orh-tr.oxvasc@nhs.net**](mailto:orh-tr.oxvasc@nhs.net) **– thank you.**

If participants using Bluetooth have no mobile phone signal, other options e.g. Wi-Fi connectivity are available, and can be set up by contacting the Oxford monitoring team.

1. **Equipment supplies**

Please ask the Oxford Monitoring team any BP queries and if you require further equipment, pre-paid postage envelopes or packaging.

**Please keep us up to date with centre contact details – names, phone numbers and addresses.**

1. **Travel**

The BP Hub will not work abroad. The BP Meter can be taken on a flight with batteries removed, in hand luggage to explain what it is.

For participants travelling abroad: If necessary, participants with internet access can be given access to manually upload weekly BP readings.

1. **Blood samples**

Please send the bloods to: Shahena Butt, PROHIBIT-ICH study, Stroke Research Centre, Russell Square House, 10-12 Russell Square, First Floor, London, WC1B 5EH

This is documented in the following places:

1. The study protocol (v3 13.06.2018), on page 27 and again on page 28
2. Patient information sheet (v3 13.06.2018), on page 2
3. The blood sampling SOP