

Meeting: PROHIBIT-ICH Site Teleconference

Date: Friday 13th March 2020

Time: 10am – 11am

Attendees: Professor David Werring (DW), Maja Dabagh (MD), Bindu Gregory (BG), Jo Howe (JH), , Michelle Wilson (MW), Ian McGurgan (IM) , Tom Moullaali (TM), Allan Macrauld (AM), Elaine Amis (EA), Con Tibajia (CT), Cyrille Cahoy (CC), Ben Jackson (BJ), Angela Welch (AW)

Apologies: Salford team, Imperial team

1. Welcome and Introductions

These monthly teleconferences are taking place to briefly update sites of study progress, recruitment, any challenges sites are facing and as an opportunity for sites to share recruitment and tips

2. Progress and Study Update

- DW: 35 participants have been recruited, this is 31% of the target number of 112 participants.
- We've had a recent flurry of recruitment activity with 5 participants recruited in February.
- If we keep this rate up we should be close to target recruitment number by the end of 2020 will follow up to be completed by the end of 2021.

3. Review of screening logs from each site and update on recruitment from each site

Cambridge

- 5 participants recruited, 3 since January 2020 and they have 3 potential participants
- Setting up of the new ICH clinic and having this has a specific clinic to find patients has facilitated recruitment.
- COVID-19: Business as usual currently

St George's

- 4 participants recruited
- COVID-19: It will affect them a lot, they will be going down to having half of the team there as the other research members will be deployed elsewhere
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UCLH

- 5 participants recruited
- In HASU they are waiting for patients to be close to discharge
- 154 screened, 10 eligible
- DW stated he had looked at scans for 5 potential participants this week and at least 3 are in the pipeline, for the 2 that can't be included the reasons are: BP too well controlled and for the second person they were on too many antihypertensives
- COVID-19: They are moving to telephone clinics and potential participants will be approached this way

Sheffield

- 3 participants recruited, 1 potential JH says she needs to chase up
- They have found BP tends to be too good to recruit a participant
- COVID-19: They have not had an update if they'll be told to do telephone clinics yet

Nottingham

- 3 participants recruited, they have screened 117 ICHs since April 2019, only 8 were eligible, 5 approached and of these 2 were not interested in taking part
- There are 4 potential participants on the rehab ward and they are waiting for things to improve for them
- Reasons participants were not eligible: Poor outcome, BP under control, Competing trial (TRIDENT)

Oxford

- 2 participants recruited, 60 screened which includes OXVASC patients also, 2 potential
- Common reasons for not being recruited: BP well controlled or on too many antihypertensives, they have had a few fatal ICH in last few months, also 1 repeat patient
- COVID-19: Business as usual currently, however, the research imaging centre may be shut down, the research team are starting to be discouraged from bringing patients in.

Glasgow

- 2 participants recruited, 2 potential participants: 1 in rehab, another is waiting for throat surgery but life circumstances (a close family member has had a stroke also) may prevent recruitment.
- COVID-19: Business as usual currently, research may not taken place but no decision taken yet by the trust, 'watching and waiting' for update from the trust, expect changes on a daily basis but screening is carrying on

Edinburgh

- 2 participants recruited, 25 participants screened since January 2020
- 15 ineligible due to having a life expectancy of <2 years.
- COVID-19: They are awaiting response from R&D on what changes there might be to the research service. They have spent the morning doing risk assessments about staff and are considering follow up over the phone.

Preston

- No participants recruited yet, 10 participants screened since January 2020, 2 potential inpatient participants – 1 will be approached when a bit better, the second patient has well controlled BP but will be approached again should this change
- Reasons why some participants can't be recruited include: 1 had aneurysm clip therefore contraindication to MRI, some aren't hypertensive bleeds or are on EOLC, 1 didn't want a MRI scan.

King's

- Top recruiting site with 6 participants recruited, with 1 potential
- COVID-19: Business as usual currently but they have the same concerns about it as other sites and they are moving to telephone follow ups. They stated that they are asking participants questions such as: 'Have you been in contact with anyone who has tested positive for coronavirus?' They are doing risk assessments.

4. Tips and challenges in patient recruitment

Tips

King's

- As top recruiter they had the following suggestions:
- Emphasising to potential participants that their ICH was caused by high blood pressure so that they realise this is a huge risk factor for further bleeds.
- Emphasising that follow up is a good way to keep in touch with the stroke team
- Generally emphasising the lasting benefits of taking part in the study so that they are happy to be followed up.
- Giving contact details so that they know you are only a phone call away if they need any further support.

Challenges

The general problem with recruitment seems to be that participants are often too unwell to take part or that their BP is well controlled or they are on too many antihypertensives.

Nottingham wondered what is the acceptable threshold for how well a patient needs to be before they can be recruited on the study. The consensus appeared to be that the participant needs to be able to manage things for themselves.

Cambridge

- Have found the study to be time intensive. It recently took 3-4 hours and 3 members to recruit a patient, time was spent on accompanying a patient to and from the MRI scanner and sorting out the BP equipment.
- St George's said they've found it takes half a day usually with 1 research team member. But believe they have been fortunate with the participants not requiring too much attention.
- Discussion between several site members that a major factor that can lead to increased time spent recruiting is when there is a new research team member who doesn't know all the ins and outs of the trial and equipment yet.
- DW would be happy to speak to Sarah Finlay to offer support and find out more details

Action point

Sarah Finlay to get in touch with us about the time intensive issue described above.

COVID-19

All sites agreed that COVID-19 is going to be a new, highly significant challenge to recruitment. DW mentioned the current advice from MHRA. Please have read of it if you haven't already:

<https://mhrainspectorate.blog.gov.uk/2020/03/12/advice-for-management-of-clinical-trials-in-relation-to-coronavirus/>

Protocol deviations are likely and we request that site teams document fully the deviations. We recommend doing as much trial related work as possible by telephone.

In terms of MRI scans: deep cleaning is likely to be required for MRI scanners and these scanners will likely be diverted to acute cases.

BP monitoring and COVID-19

Questions arose about whether BP monitoring equipment can be allocated without face to face interaction and sent directly from Oxford to the patient's home.

MW: You would need to be confident that the participant can do all the steps.

IM: Not really, one would need good instructions.

Action Point

Produce a FAQ document with COVID-19 related advice with regards to modifying recruitment via telephone as much as possible and whether obtaining/sending back BP equipment straight from/to Oxford is possible or not.

5. Tips and challenges in patient follow up

COVID-19: will be a huge challenge for all sites with regards to getting participants to return to hospital for follow up visits. For 12 month follow up MRI scanning as mentioned in the previous section also applies here, the service may stop for many sites.

BP monitoring and COVID-19

DW: Would the participants be able to manage setting up of 24 ABPM themselves at 3 months follow up at home?

MW: They would need to have the cuff on the right way round, good training would be needed , it might be better to offer this than have no data coming in at all.

Action Point

Include in the FAQ document mentioned above whether or not follow up BP monitoring equipment can be sent home at 3 month and 12 months instead of face to face visits.

6. Amendments

Summary of amendments:

1. Removal of inclusion criteria 4: 'For patients recruited in hospital there should be a plan for home discharge (not to a nursing or care home) after their inpatient stay, or living at home at the time of recruitment'
2. Reducing the age limit to 30 and above
3. Patients can be identified from site databases that contain patients who have had a previous ICH at any time, including databases of participants included in previous clinical trials (subject to agreement with the Chief Investigator of the other trial). Potentially eligible patients can be contacted by telephone, email or post, and will be invited to the site hospital for screening and to obtain informed consent.
4. We will also provide posters (included in list of enclosed documents) which give information on the study, to be displayed at participating sites (including NHS PIC sites, see below); suitable locations include doctors or nurses offices, noticeboards, or in outpatient clinics.
5. NHS Patient Identification Centre (PIC) sites will be included in the study. These sites will be NHS sites; the staff at these sites will identify potential patients and inform the study team at the local PROHIBIT-ICH recruiting sites.

Progress on amendments:

England:

Awaiting green light to implement the amendment from Oxford and Cambridge. All other sites have the green light.

Scotland:

R&D in Glasgow and Edinburgh have been notified of the substantial amendment. The amendment can be implemented in Glasgow. Edinburgh R&D state they have a backlog.

Action point

MD to follow up on the decision of remaining R&Ds.

7. Imaging data

We have reviewed all images to date. Glasgow has been asked to rescan a patient due to non isotropic images, Nottingham has also as part of the edges of the brain were missed for some sequences. Cambridge were asked to reupload scans using Chrome and zipped files which resolved the issue we had viewing their images.

Reminders:

- Make sure you are using Chrome or Firefox, Internet Explorer will not work.
- Ensure your scans are compressed into a zip file before uploading.
- We do not accept CDs with the scans on them.
- Please also remember to refer to the imaging manual and check the radiographers are doing this too.

8. Any other business

BP equipment and COVID-19

- MW: If there is any suspicion of a patient testing positive for COVID-19 please let Oxford know before using BP equipment
- Equipment will need to be washed at 60 degrees. When returning equipment please double bag before sending it back.
- An update about the BP equipment recommendations will be made next week

DW: We were encouraged by the February recruitment figures, however the pandemic will prove a big challenge to recruitment of new participants as well as fulfilling all the requirements of each follow up visit.

Next teleconference in 1 month's time: Date TBC