

REACT-AVB Newsletter



Randomised controlled trial of Early transjugular intrahepatic portosystemic stent-shunt in Acute Variceal Bleeding

Issue 2

Autumn 2024

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*National Institute for
Health Research*

Welcome to the second issue of the REACT-AVB Newsletter!

A very warm welcome to all our collaborators! As we reach the halfway point of the pilot phase, we would like to provide you with an update on trial progress so far. Thank you for all your help and support so far and, as ever, if you have any questions please don't hesitate to contact the Trial Team.

Message from Chief Investigator, Professor Dhiraj Tripathi and Co-Chief Investigator Dr David Patch



Professor Dhiraj Tripathi



Dr David Patch

Dear Colleagues

On behalf of the REACT-AVB Trial Management Group (TMG), we would like to welcome you to the second REACT-AVB newsletter. We are very grateful to all collaborators for their contributions. REACT-AVB is very much your trial.

In addition to Queen Elizabeth Hospital Birmingham (QEHB), Royal Free Hospital (London), and John Radcliffe Hospital (Oxford), we welcome Queen's Medical Centre (Nottingham), Whittington Hospital (London), Derriford Hospital (Plymouth), Royal Infirmary of Edinburgh, Glasgow Royal Infirmary and Queen Elizabeth University Hospital (Glasgow) as recruiting sites. Twelve patients have so far been recruited thanks to the research teams working tirelessly to screen patients. We are on track to successfully complete the pilot.

Please find below all the other sites in set-up. We are hopeful that we will be able to open more sites soon. We would like to thank you for all your efforts in obtaining local approvals.

We are offering regular site initiation virtual sessions which sites are required to attend after viewing the SIV slides. This is an essential step prior to sponsor greenlight to open your site. We are also offering monthly drop-in sessions to recruiting sites to discuss specific queries with the REACT-AVB team. Please review the FAQs at the end of this newsletter which reflect recent queries brought to our attention.

A REACT-AVB update Webinar is also planned and we will send you further details shortly.

We will keep you updated of progress with regular newsletters. In the meantime, please do not hesitate to contact us or other members of REACT-AVB TMG if you have any queries.

Kind regards, Dhiraj & David

Site Update

Sites Currently Open

We are extremely pleased to announce that we now have **nine** centres open to recruitment!

SITES OPEN	HUB/SPOKE	PRINCIPAL INVESTIGATOR (associate PI)	DATE OPENED
Queen Elizabeth Hospital (Birmingham)	Hub	Dr Matthew Armstrong (aPI: Dr Sanchit Sharma)	28/02/2024
Royal Free Hospital (London)	Hub	Dr David Patch (aPI: Dr Jemima Finkel)	28/02/2024
John Radcliffe Hospital (Oxford)	Hub	Dr Jeremy Cobbold	10/04/2024
Queen’s Medical Centre (Nottingham)	Hub	Dr Naaventhana Palaniyappan	14/05/2024
Royal Infirmary of Edinburgh	Hub	Professor Peter Hayes (aPI: Dr Sarah-Louise Gillespie)	26/07/2024
Whittington Hospital (London)	Spoke to Royal Free	Dr Evangelia Fatourou	19/09/2024
Derriford Hospital (Plymouth)	Hub	Dr Matthew Cramp	24/09/2024
Queen Elizabeth University Hospital (Glasgow)	Hub	Dr Judith Morris	04/10/2024
Glasgow Royal Infirmary	Hub	Professor Adrian Stanley	04/10/2024

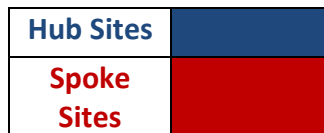
A huge ‘Thank you!’ to all our colleagues at these sites for your hard work and effort that has enabled this to happen.

Sites in Set Up/ Site Set Up Process



Figure 1 Map of Open and Interested Sites

Hospitals continue to express interest across the U.K, with sites progressing through set up in all four nations.



Of the 50 sites that have expressed interest in the trial (in addition to the nine open sites):

- ❖ 26 have returned completed feasibility forms
- ❖ 17 Hub sites have received their Local Information Pack
- ❖ 6 Spoke sites have received their Local Information Pack

Several sites are in the final stages of set up and are due to open imminently. The pilot phase aims to open **20 centres** by the end of **February 2025**. **In order to meet our pilot target, we need your support!** If you have been provided with a feasibility form or LIP pack, could we please kindly ask you to return any requested documentation at your earliest convenience. Whilst we will always outline outstanding documentation in our site-specific correspondence, below is a brief outline of the documents required from sites/ steps to complete to progress to Green Light Approval.

Documents required from sites/ steps to complete for Green Light Approval

- Completed feasibility form
- Localisation of patient facing documentation
- Completed Organisation Information Document (OID)
- Fully executed site agreement (mCNA)
- Protocol signature page, signed by the PI
- Confirmation of Capacity and Capability/ Research Management Approval
- CVs and GCP certificates (signed and dated/ up to date in line with local Trust policy) for all site staff listed on the delegation log
- Completed delegation log
- SIV: All staff listed on the delegation log to have watched the pre-recorded site initiation training (self-certification of training completion required via presentation link)
- SIV: Attendance at a live virtual Q&A session is mandatory for the PI and Associate PI prior to opening, but we recommend any site staff involved in trial delivery attend

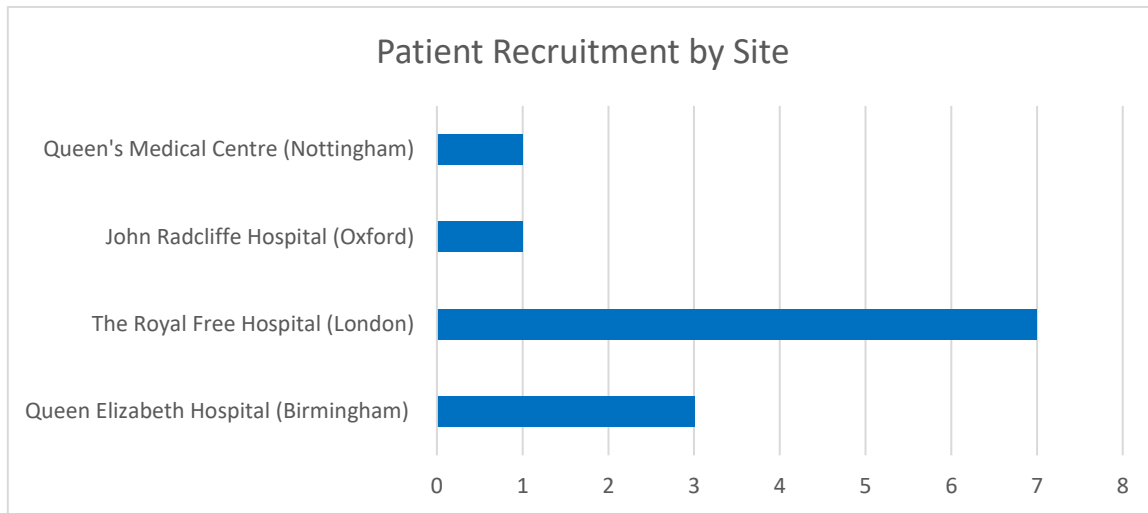
Thank you again to everyone for your help with set up, it is very much appreciated.

If you are interested in participating in REACT-AVB but haven't been in touch yet, please visit the REACT-AVB website (www.birmingham.ac.uk/react-avb) or contact the REACT-AVB Trial Office (react-avb@trials.bham.ac.uk), to obtain a copy of the feasibility form

Recruitment, Patient Screening and Data Returns

Recruitment Update

Twelve participants have now been recruited to the REACT-AVB trial, with the graph below detailing recruitment by site:



Data collated from the monthly screening logs show that over 50 patients have been reviewed for the trial since recruitment commenced. Thank you so much to our colleagues at all open sites for continuing to look for suitable patients and recruit. We aim to recruit **35 patients** by the end of the **12-month pilot phase (28th February 2025)**- together we can make this happen!

Screening Logs

Our Trial Management Group (TMG) oversight committee has been extremely impressed by the screening data returned from open sites. This information provides a valuable insight into the eligibility criteria potential patients are failing to meet, and the reasons eligible patients are not randomised. The REACT-AVB Trial Team will continue to request **completed screening logs** are returned at the **end of each month**, to allow collation of data prior to the next TMG meeting. Our Trial Steering Committee (TSC) and Data Monitoring Committee (DMC) are also due to meet in October 2024, and so it is important we can provide an accurate reflection of the patient population screened for these meetings.

Case Report Form and Data Clarification Form Returns

We have been pleased with the form return rates and resolution of data queries so far and we thank you for your engagement with the trial. At the time of writing this newsletter, **over 90%** of expected forms have been returned for each CRF category- a wonderful achievement! As the TSC and DMC meetings draw near, we may contact you regarding additional/ outstanding data queries. We would very much appreciate your prompt response to this correspondence.

In Other News...

Q&A Sessions/ Drop in Sessions/ Webinar

The REACT-AVB Trial Team now offer two types of virtual meeting:

- ❖ Site Initiation Q&A Sessions
- ❖ Monthly Open Site Drop In Sessions

The latter provides an opportunity for open discussion of any queries, and the chance to share best practice between sites. All sessions are listed on the website with their associated Zoom link: [Trial Resources - University of Birmingham](#). We ask that you please register in advance of any of these sessions via the Zoom link so that we can monitor attendance and prepare documentation as required.

In addition to these sessions, we hope to host a **trial webinar** on **Monday 25th November 2024** between **1.00pm and 2.00pm**. More details to follow.

NIHR Associated PI Scheme

The REACT-AVB trial is registered with the Associate PI Scheme and is available to receive Associate PI trainee applications. The scheme provides clinical staff with the chance to experience what it means to work and deliver a NIHR portfolio trial under the mentorship of a Local PI. Participating healthcare professionals will receive formal recognition of engagement in NIHR Portfolio research studies through the certification of Associate PI status, endorsed by the NIHR and Royal Colleges. For more information please visit: [Associate PI Scheme - FAQs | NIHR](#).

A Friendly Reminder: Changes to Site Staff and Maintenance of Delegation Logs

A friendly reminder to please notify the BCTU Trial Team of any changes of staff as soon as they occur. This will ensure we can maintain accurate records as to the staff working on the trial at each Trust and ensure site staff have received the appropriate trial training. If a member of staff leaves the trial, this should be documented within the "To" date of duties column on the delegation log. CVs and GCP certificates should be up to date as per local Trust policy, and we kindly ask that updated documentation is forwarded to the BCTU Trial Team as and when it becomes available.

If any other changes are made to a completed delegation log, can we please ask that each amendment is initialled and dated, whilst still maintaining the legibility of the entry. If an entry becomes unclear due to the number of changes made, we would request that a complete new entry is made onto the log.

Upcoming Meetings

REACT-AVB is due to be presented at the Midlands Gastroenterological Society Autumn Conference on Friday 15th November 2024. Please do pop along and say hello if you are in attendance!

Frequently Asked Questions (FAQ)

A continually updated listed of Frequently Asked Questions are available on the trial website: [Trial Resources - University of Birmingham](#). Here is a small selection of questions that have been asked recently:

What are the acceptable methods of signature for the mNCA?

DocuSign and other electronic signature software is acceptable, along with wet ink signature. We are unable to accept a signature that has been copied and pasted within the MS Word document.

Which members of staff need to be listed on the delegation log? Should the Radiologist and Anaesthetist performing the TIPSS procedure be included?

The research staff listed on the delegation log should be those who are able to undertake the tasks outlined in the log. It is the responsibility of the PI to confirm that those that are listed on the delegation log are qualified to undertake such activities. All tasks listed on the delegation log must be covered by at least one member of staff at a site for Green Light approval to be granted. We do suggest that sites may want to add sub-investigators (for if the PI is not available) and ideally a senior gastroenterology/hepatology colleague. This is particularly important when covering causality review during adverse event reporting. As the TIPSS procedure is carried out within routine care, an interventional radiologist/ITU consultants/ anaesthetist is not required on the delegation log.

Can both a PI and co-PI be named on the delegation log?

No. Our agreement (mNCA) only allows for one PI at each site who is solely identified for completion of the delegation log and trial oversight. Any other clinicians may be listed as sub-Investigators.

For the Associate PI Scheme, can there be two or more simultaneous Associate PI (aPI) Trainees who are amid their 6-month tenure, at the same site, at the same time?

Most PIs will only mentor one aPI Trainee at a time. However, if you as the local PI are happy to mentor more than one aPI Trainee at a time then NIHR will allow this. We are led by the capacity of the local PI. If a site has the capacity to support multiple aPIs, please contact the BCTU trial office to confirm and we will inform the NIHR team.

Will staff only perform a diagnostic endoscopy if there is suspected bleeding, or can there be other reasons a diagnostic endoscopy has been performed?

Whilst the index endoscopy will be performed due to a history of bleeding, subsequent endoscopies may be carried out for several reasons i.e. where bleeding is suspected, as part of the banding programme in the SoC arm, or if there is a crossover from SoC to the TIPSS arm.

Does the 4-day window post diagnostic endoscopy to TIPSS treatment include or exclude weekends?

It is expected that the TIPSS procedures will be carried out during working hours; it is not a salvage or rescue TIPSS since patients are stable. Therefore, if a site can only offer TIPSS during working hours that is acceptable. The clock starts at the time of diagnostic endoscopy and should include weekends, therefore the 4 days should allow for planning a TIPSS procedure on a Monday if a patient has diagnostic endoscopy and is randomised on a Friday.

If a patient is randomised to the TIPSS arm and then it is not possible to offer TIPSS within the 4-day window, should the procedure still be conducted?

If a patient is randomised to the TIPSS arm and, due to an unforeseen circumstance it was not possible to offer TIPSS within the 4-day window, then we advise that the procedure can still go ahead if the opinion of the clinical team supports the intervention. We are monitoring adherence to the time frame as part of the pilot, which will inform any future protocol amendments.

REACT-AVB Key Contact Details

Need some advice? We're happy to help!

Title	Contact	Email
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Visit the [REACT-AVB Website](#) for trial information, training and documentation.

Please also follow us on Twitter/X <https://twitter.com/AvbReact>

Thank you for taking the time to read the REACT-AVB Newsletter!

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