REACT-AVB Newsletter

Randomised controlled trial of EArly transjugular intrahepatiC porTosystemic stent-shunt in Acute Variceal Bleeding

Issue 1	Spring 2024

In This Issue

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

NHS National Institute for Health Research

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

In order to keep you informed with the REACT-AVB trial progress, we have produced this newsletter which highlights the recent developments that have been made. We will circulate regular newsletters to keep you updated throughout the duration of the REACT-AVB trial.

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 first REACT-AVB newsletter. First and foremost, we would like to thank every single collaborator for supporting REACT-AVB. REACT-AVB is very much your trial.

REACT-AVB is now live having opened at the Queen Elizabeth Hospital Birmingham (QEHB), Royal Free Hospital on 28th February 2024 and John Radcliffe Hospital, Oxford on 10th April 2024. We are delighted to inform you that the Royal Free Hospital, under the leadership of Dr David Patch and his team have recruited 3 participants, closely followed by QEHB site which has recruited 2 participants under the leadership of Dr Matthew Armstrong and his team.

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.

The protocol paper has just been published and the link is provided in this newsletter.

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.

With kind regards

Dhiraj & David

Site Updates

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

List of Interested Sites

SITE	NAME OF PI
Addenbrooke's Hospital	Dr Teik Choon See
Aneurin Bevan University Health Board (Royal Gwent Hospital & The Grange University Hospital)	Dr Fidan Yousuf
Birmingham Heartlands Hospital	Dr Andrew King
Borders General Hospital	TBC
Broomfield Hospital	Keval Naik
Derriford Hospital	Matthew Cramp
Forth Valley Royal Hospital	Dr Joanna Leithead
Freeman Hospital	Dr Steven Masson
Glasgow Royal Infirmary	Professor Adrian Stanley
Gloucestershire Royal Hospital	Dr Coral Hollywood
Good Hope Hospital	Dr Faisal Khan
Kings College Hospital South	TBC
Lincoln Country Hospital	TBC
Manchester Royal Infirmary	Dr Imran Patanwala
Morriston Hospital	Dr Jagadish Nagaraj
New Cross Hospital	Sarah Townsend
Norfolk and Norwich University Hospital	Dr Syed Alam
Northern General Hospital	Dr Laura Harrison
Northwick Park Hospital (London)	Dr Jayshri Shah
Queen Elizabeth University Hospital (Glasgow)	Dr Jude Morris
Queens Alexander Hospital	Richard Aspinall
Queens Medical Centre	Dr Naaventhan Palaniyappan
Royal Glamorgan Hospital	Dr David Samuel
Royal Infirmary of Edinburgh	Professor Peter Hayes
Royal Liverpool Hospital	Dr Omar Elshaarawy
Royal United Hospital Bath	Terence Farrant
Royal Victoria Hospital	Dr Roger McCorry
Southmead Hospital (Bristol)	Dr James Maurice
St George's Hospital	Dr Sarah Hughes
St James University Hospital Leeds	Dr Victoria J Appleby
St Johns Hospital	TBC
St Mary's Hospital (London)	Dr Ameet Dhar
The Royal Victoria Hospital (Scotland)	TBC
University Hospital Coventry	Esther Unit
University Hospital of Wales	Dr Tom Pembroke
Western General Hospital	TBC

SITE	NAME OF PI
Whittington Hospital	Dr Evangelia Fatourou
York Hospital (Leeds)	Dr Robert Driver
Addenbrooke's Hospital	Dr Teik Choon See
Aneurin Bevan University Health Board (Royal Gwent Hospital & The Grange University Hospital)	Dr Fidan Yousuf
Birmingham Heartlands Hospital	Dr Andrew King

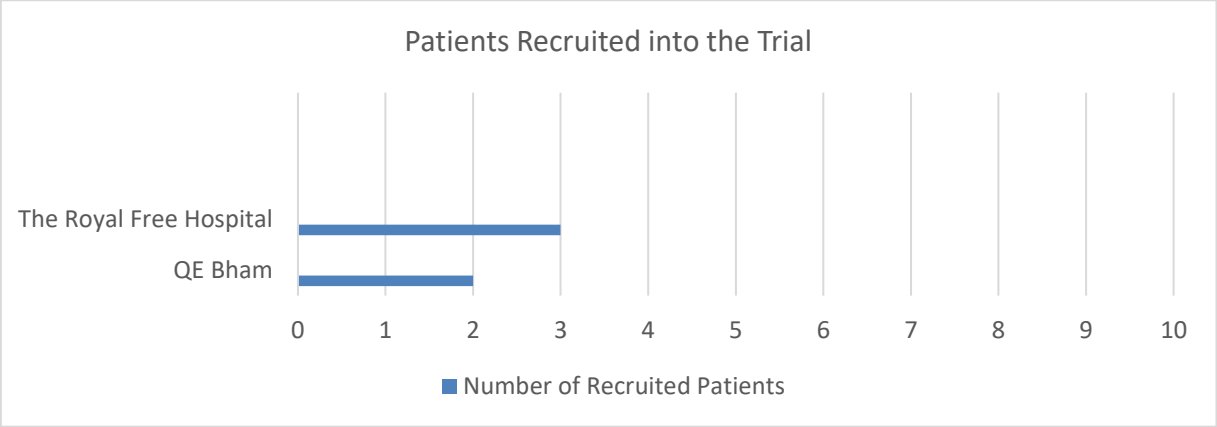
Sites Currently Open

We are over the moon to announce that the first 3 sites of the REACT-AVB trial are now open.

SITES OPEN	DATE OPENED
Queen Elizabeth Hospital	28/02/2024
Royal Free Hospital	28/02/2024
John Radcliffe Hospital	10/04/2024

We would like to say a massive 'Thank You!' to all the site team members for your combined efforts and hard work to enable these sites to open, along with the site team members who are currently working on opening your sites.

Recruitment Update



Site Map

We have had a fantastic response from sites across the UK, registering expressions of interest in the REACT-AVB trail – Thank you! In total 48 Feasibility Form have been sent out.

Thank you to all the sites that have returned completed Feasibility Form – we look forward to having you on board soon.

Figure 1 Map of Open and Interested Sites

Hub Sites	
Spoke Sites	

What Do I Need Before the Trial Can Open At My Centre?

- **Return feasibility form -** When we receive your completed feasibility form back from you (PIs CV and GCP Certificate), we will be able to send you the Local Information Pack (LIP). Once you have confirmed receipt of the LIP, we will provide you with further instructions.

- **Current CVs (signed within the last 12 months):** required for the PI, Associate PI, plus any other staff that will be performing research activity for the trial at your site.

- **Good Clinical Practice (GCP) certificates:** required for the PI, Associate PI, plus any other staff that will be performing research activity for the trial at your site.

- **Watch the pre-recorded SIV presentation training slides:** required for the PI, Associate PI, plus any other staff that will be performing research activity for the trial at your site. This will be sent via email after the LIP pack has been shared with you. **Please refer to further information below**

- **Attendance at a live virtual Q&A session:** Required for the PI and Associate PI prior to opening, but we recommend any involved in trial delivery attends. **Please refer to further information below**

- **Completed Delegation log:** this will be sent in your LIP **for site to complete.**

- **Protocol signature page, signed by the PI:** this will be sent in your LIP.

Site Initiation Training and Q&A Session

- When we send your site the LIP you will receive instructions to what your site need to do next.

- Site initiation training will be in the format or pre-recorded video presentation slides followed by live virtual Q&A sessions with the Chief Investigator and trial office team, hosted on Zoom.

- You will be asked to self-certify that you have watched the pre-recorded video as evidence of trial training. **This is a compulsory prior to joining a Q&A session.**

- **You will then need to register in advance** to attend one of the Q&A sessions so we can prepare the relevant documents to be discussed; **PLEASE DO NOT** share the Zoom meeting link details to team colleagues, as the registration will provide us with a record of attendees for report writing purposes.

- It is **mandatory** for the PI and any Associate PIs to attend a Q&A session. For your site to open this must be done. We recommend that anyone else involved in research activities to also join in the session, but this is not mandatory.

Latest News

We are pleased to announce that the protocol paper has now been published on BMJ Journals on 22 March 2024. Thank you to all collaborators for your assistance. To review the paper, please follow the link: https://doi.org/10.1136/bmjgast-2023-001314

NIHR Associate PI Scheme

We are pleased to confirm that REACT-AVB is now registered with the Associate PI Scheme and is available to receive Associate PI trainee applications. The scheme is aimed at people who would not normally have the opportunity to take part in clinical research in their day-to-day role. You will have 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

Frequently Asked Questions (FAQ)

Which type of site will you recruit from?
We will be recruiting patients from acute NHS Trusts and Health Boards in the UK that admit and manage patients with acute variceal bleeding.

Has a recruitment target been confirmed?
The recruitment target is 294 patients across 30 sites in the UK. We expect sites to recruit three or more participants per year. If this is not possible, please do reach out to the team to discuss further with the CI.

When is the recruitment end date?
28/02/2028

When is the end date for the study activities? (i.e. "last patient visit" completed and study is ready to be archived.)
28/08/2029

The dates provided above have been projected based upon the first site opening. Please note that the trial has an internal pilot (1 year) and any decision going forward will be based on how the pilot goes and if we move to full trial. For further information regarding the progression criteria for the pilot, please see section 2.1 of the Protocol

Is there any pharmacy/ CRF/ CRF labs involvement?
There is no CRF/Labs/pharmacy involvement. The main delivery team is imaging.

Will the bloods be sent to the trial's office?
No, these will be classed as standard of care and sites will only be required to record the results onto the CRF.

Can you confirm that all bloods are standard of care and there is no requirement for any additional local lab processing?
'Yes', bloods are standard of care and 'no' requirement for any additional local lab processing.

Which Blood tests do I need to record on the Baseline CRF?
We advise that the most recent standard of care bloods are used within a 48h timeframe prior to randomisation.

Should a patient be suitable to be enrolled in the study would we be able to check the availability of TIPSS within 4 days prior to enrolling them and if for whatever reason TIPSS was not feasible we would not enrol them in the study?
No. We cannot just select patients depending on whether there's availability for TIPSS or not. If we assess feasibility of 4-day window prior to randomisation, it could introduce selection bias. We want to assess how feasible the 4-day window is in "real world" situation. This is the big strength of REACT-AVB trial over other similar RCTs. If, however, during the trial, it becomes apparent at the HUB site, that TIPSS is completely not possible due to unforeseen circumstances e.g. the interventional radiologist was unavailable due to sickness and no replacement could be found, then it would make sense to suspend recruitment until the TIPSS service can resume. We will allow provision for this and the site in question will be asked to discuss this with the CI.

Are any devices to be provided for the study?
No devices are required or will be provided for the trial.

REACT-AVB Key Contact Details

Need some advice? We're happy to help!

Title	Contact	Email
Chief Investigator	Professor Dhiraj Tripathi	dhiraj.tripathi@uhb.nhs.uk
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Senior Data Manager	Charmaine Hunt	c.e.hunt@bham.ac.uk
Team Leader	Elizabeth Brettell	e.a.brettell@bham.ac.uk

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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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