CALIBRE Newsletter

Carvedilol versus variceal band ligation in primary prevention of variceal bleeding in liver cirrhosis

Issue Eight | **April 2020**

In this issue:

Welcome to our April issue of the CALIBRE Newsletter!

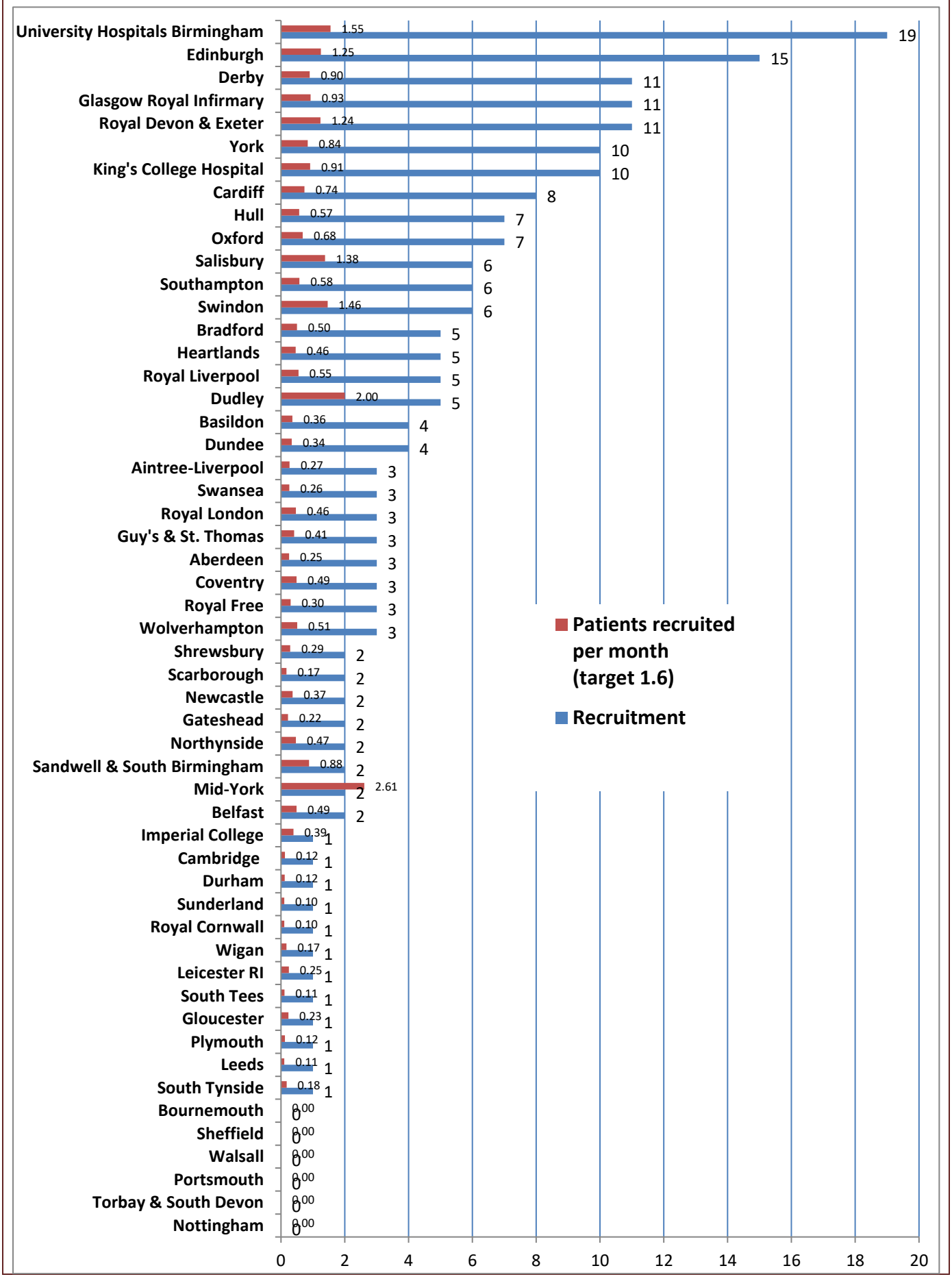
First of all, we hope you are all keeping safe and well in these unprecedented times.

1. A Message from the CALIBRE Trials Team

As you are aware, CALIBRE recruitment was paused on 24 March 2020 due to the COVID 19 pandemic. All BCTU staff are now working remotely so please do not post CRFs. They can be emailed to us securely using the University of Birmingham's Bear Datashare – please contact us via calibretrial@trials.bham.ac.uk to create a folder for your site.

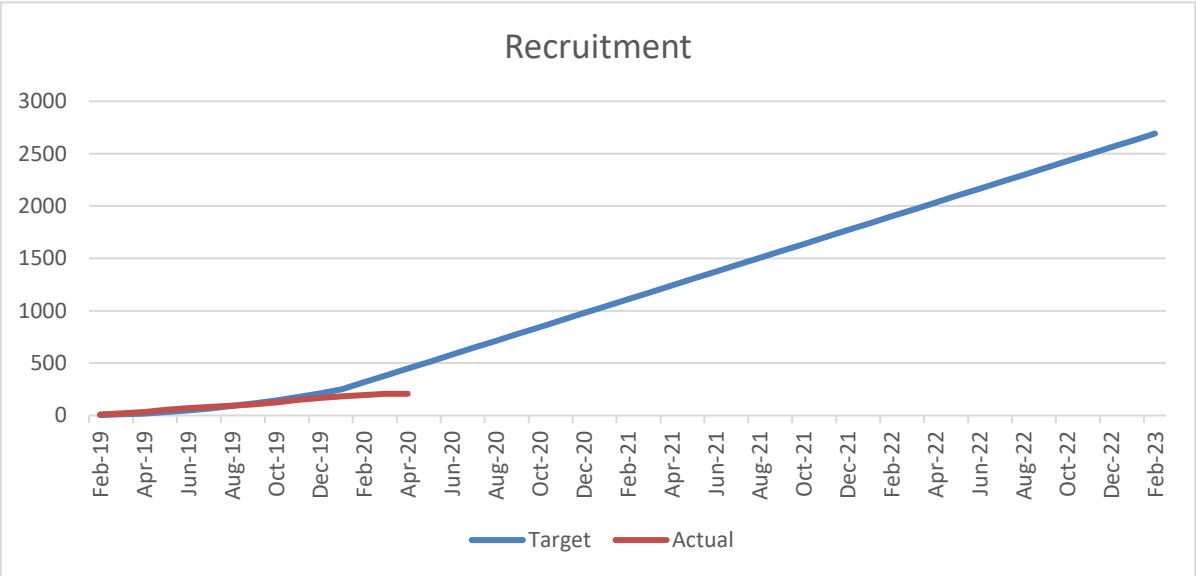
Follow up appointments can be carried out by telephone including the EQ-5D-5L form where the majority of the CRF can be completed the emphasis is to capture the primary outcome. We understand that this continues to be a challenging time for all of you and your hospitals and thank you for your continued support.

2. Recruitment

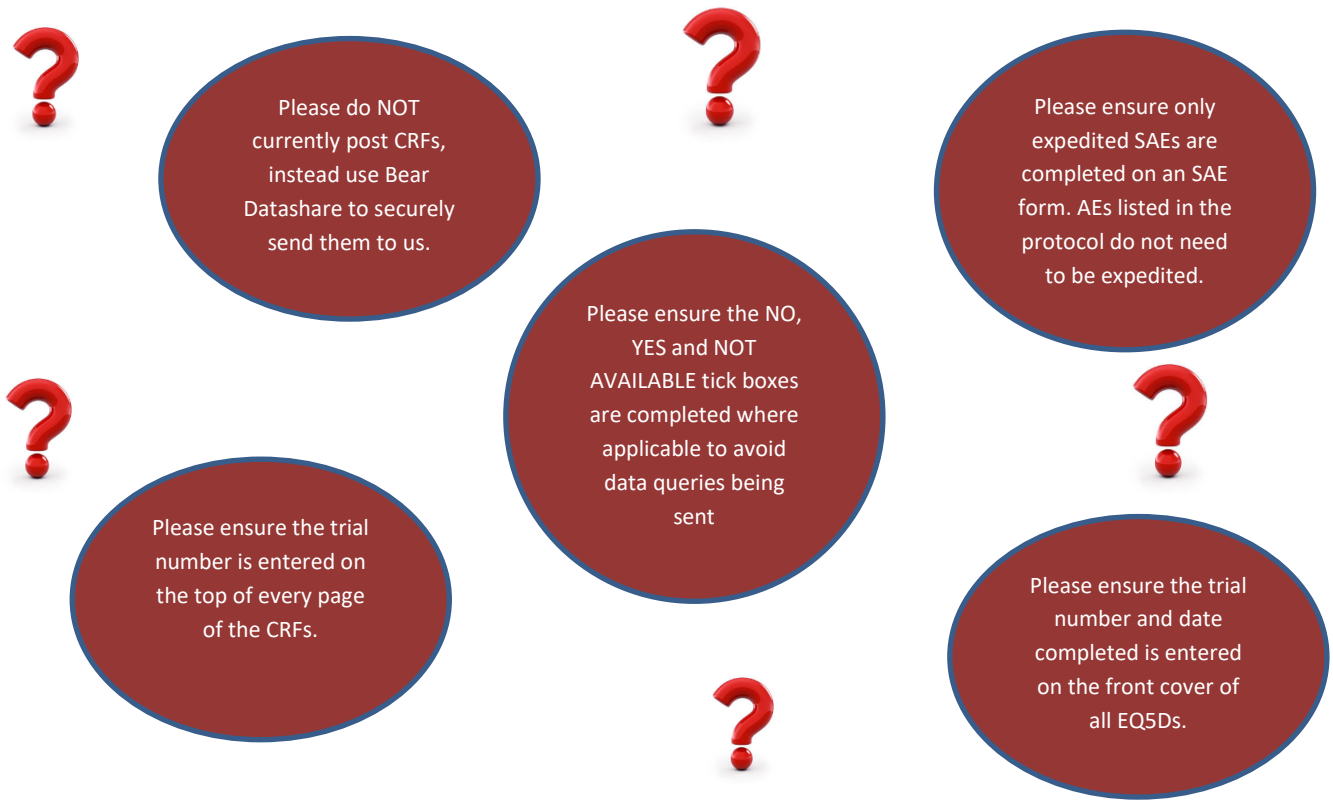


Recruitment was paused at 207 participants and 57 open sites, so UHB continue to maintain their lead as the top recruiter! Obviously, this can all change once recruitment is open again and we will be providing some tasty incentives to help push our recruitment numbers up!

We are now in the main phase of the trial and will be opening new sites as soon as we are able to.



3. Data Queries



4. FAQs

Q: Could patients already on a selective beta blocker take part in CALIBRE?

A: *Patients already on selective beta blockers could take part in CALIBRE, however after randomisation if they fall into the carvedilol arm they will not be able to continue their selective beta blocker, if in VBL arm they could. This will be at clinician's discretion if it is safe to randomise such patients who could discontinue beta blocker use if randomised to the drug arm.*

Q. If patients are on non-selective beta blockers i.e. carvedilol, propranolol, nadolol for short term i.e. less than 7 days and have now stopped taking the medication could they be included?

A. *Patients who have already in the past or are currently taking a non-selective beta such as carvedilol, propranolol, nadolol will not be eligible to take part in CALIBRE regardless of time. This also applies to a patient who has in the past undergone VBL. This is clarified further in the new revision of the CALIBRE protocol version 2.0 available via* **CALIBRE Website** *also any previous TIPSS patients or organ transplant patients will be excluded.*

Q: If a patient has had a previous liver resection for HCC, would that make them ineligible for CALIBRE?

A: *As long as the patient has clear evidence of cirrhosis in the background liver and the 1 year survival is not affected by previous surgery (assuming to be curative) then they can be included.*

5. Other New

- We love hearing from our sites so please do let us know how you are getting on and what plans your hospital has for post COVID-19.
- We will be providing short refresher training videos online post COVID-19.
- We would like to say a huge thank you to you all for your collective efforts during this very difficult and unprecedented time. #StaySafe

If you are interested in participating in CALIBRE but have not been in touch yet, please visit the CALIBRE website (www.birmingham.ac.uk/calibretrial) (http://www.isrctn.com/ISRCTN73887615) or contact the CALIBRE Trial Office (calibretrial@trials.bham.ac.uk), to obtain a Practical Arrangements Form also available via the CALIBRE Trial website.

CALIBRE Trial Details

Sponsor:
University of Birmingham

Funding:
National Institute for Health Research (NIHR)
HTA Programme

EudraCT no.: 2018-002488-24
REC ref no.: 18/NE/0296
IRAS ref no.: 248487
Funder's ref no.: 16/99/02
Sponsor ref no.: RG_17-229

CALIBRE Key Contacts

Need some advice? We're happy to help!

See the 'trial details' section and don't forget to check out:

The CALIBRE Website for trial information, training and documentation

The CALIBRE Twitter Feed for updates and discussion; Follow us @calibretrial

Chief Investigator:	Dr. Dhiraj Tripathi	dhiraj.tripathi@uhb.nhs.uk
Senior Trial Manager:	Dr. Khaled Ahmed (Abdul)	k.ahmed.1@bham.ac.uk
Senior Data Manager:	Lisa Holden	l.m.holden@bham.ac.uk

CALIBRE Trial Office:

Website: www.birmingham.ac.uk/calibretrial
E-mail: calibretrial@trials.bham.ac.uk

The CALIBRE Trial team are working remotely, please email the above if you want to speak to someone and a team member will call you back as soon as someone becomes

Online Randomisation – Paused until further notice

Upcoming Trial Office Closures:

The **CALIBRE** Trial Office at BCTU will be closed on Friday 8th May for the Bank Holiday.

available. If urgent then please call the trial manager on 07951780276.

Expedited **SAEs** should continue to be reported to the CALIBRE Trial Office within 24 hours of an investigator site becoming aware of an SAE. This should be via email to the CALIBRE trial inbox copying in the trial manager. The CALIBRE SAE Form can be found at: https://www.birmingham.ac.uk/research/bctu/trials/portfolio-v/CALIBRE/investigators/documentation.aspx

Thank you for taking the time to read our CALIBRE Newsletter!

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NIHR | National Institute for Health Research