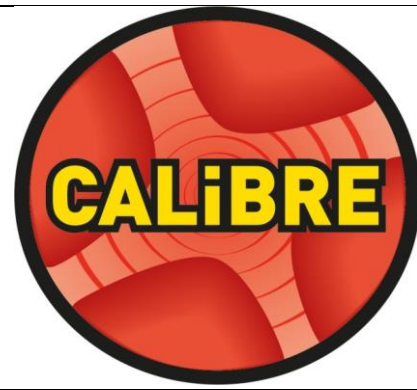


CALIBRE Newsletter



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

Issue 16

Summer 2021



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Welcome to our 'Summer 2021' issue of the CALIBRE Newsletter!

We are delighted to tell you that recruitment into the trial will soon recommence. We would like to take this opportunity to thank all of you for your hard work and commitment over what has been an extraordinary last 18 months.

1. A Message from the CI, Prof. Dhiraj Tripathi

Dear Colleagues

I would like to update you about the status of CALIBRE.

First and foremost, on behalf of the CALIBRE Trial Management Group (TMG), I would like to thank all the collaborators for the support at this challenging time. We appreciate the additional efforts in the face of unprecedented pressures.



CALIBRE completed its one-year pilot in January 2020, having opened a remarkable 55 sites, far exceeding the proposed 20 sites. This is all thanks to the incredible synergies between the Sponsor and collaborating sites. We continued to recruit until March 2020, when we had recruited 207 participants from 57 live sites. CALIBRE has been paused to recruitment since then due to the impact of the pandemic.

It gives me great pleasure to inform you, that after discussion with the funder, CALIBRE will now reopen to recruitment in early Autumn 2021. I am also very pleased to inform you that over 40 sites are now ready to go live, which is remarkable, and testament to the great effort from our collaborators and research teams. CALIBRE has also registered for the associate PI scheme, so please do encourage your trainees to join.

With the restart of recruitment, there will be another six-month pilot phase and some changes to the protocol. The six-month pilot is very important and will be used to inform funding decisions. I, along with the CALIBRE team will be offering refresher webinars, and regular drop in virtual session throughout the pilot to help with any queries and overcome barriers to recruitment.

Finally, I would like to thank the TMG who have worked tirelessly to support CALIBRE. Particular thanks to Abdul who will sadly be leaving us as Senior Trials Manager at BCTU. I wish him well in his future post. I would also like to thank the Trial Steering Committee and Data Monitoring and Ethics for their most helpful advice.

Many thanks and take care.

A handwritten signature in black ink, which appears to read 'Dhiraj Tripathi'. The signature is fluid and cursive.

Prof Dhiraj Tripathi

2. Trial Restart and Important Updates



As we look forward to reopening CALIBRE to recruitment, we wanted to let you know of some important updates

The trial will restart its 'pilot phase' where recruitment at sites will be carefully monitored by the funder.

Thank you to those sites that have already returned their Restart Checklists.

If you have not already returned your Restart Checklist please can you do so as soon as possible.



There will an update to the protocol, PIS, ICF, GP Letter and CRFs.

Timing of the carvedilol safety visit is changing from four to two weeks post randomisation. Other key updates to trial documentation will be communicated in advance of site reactivation.

Refresher training will be available.

We will also be running a series of webinars together with the CI, Prof Dhiraj Tripathi, with interactive Q&A sessions.

Invoicing for 'per patient payments' is changing

Please ensure **all** invoices for per patient payments detail the participant numbers and are sent only to the CALIBRE mail inbox – calibretrial@trials.bham.ac.uk
Invoices that do not contain participant numbers will not be processed.

Please pass this information on to your respective finance teams.

NIHR Associate PI Scheme

CALIBRE is now registered with the NIHR's Associate PI Scheme, which will provide a great opportunity for Junior Doctors to become PIs of the future. It also provides formal recognition of a trainee's engagement in NIHR portfolio research studies.

If you know of a trainee interested in participating in this scheme, prior to application to the NIHR please ensure that they provide the CALIBRE Trial Office with a current CV and GCP Certificate.

To apply, please follow the link: [NIHR Associate PI Scheme Applicant Registration Form](#)



If you have questions about any of the above, please contact the CALIBRE Trial Office.

Sites ready to reopen

UHB	Torbay & South Devon
Cardiff	King's College Hospital
Belfast	Leeds
South Tees	Leicester
Walsall	Mid Yorkshire
Hull	Northtyneside
South Tyneside	Oxford
Wigan & Leigh	Plymouth
Sandwell & City	Portsmouth
Aberdeen	Royal Cornwall
Aintree-Liverpool	Royal Devon & Exeter
Basildon	Royal Glamorgan
Basingstoke & North Hampshire Hospital	Royal Liverpool
Derby	Sheffield
Dudley	Southampton
Durham	St. Georges
Guy's & St. Thomas	Sunderland site part of South Tynside
Cambridge	Newcastle
Dundee	Nottingham
Edinburgh	Wolverhampton
Glasgow Royal Infirmary	York

3. Data Management Reminders

Some helpful hints to make the data management process run smoothly...

Please ensure only SAEs, defined by the CALIBRE protocol as being '**expedited**' are reported on a SAE Form.

(S)AEs defined as '**non-expedited**' in the CALIBRE protocol do not need to be reported on a SAE Form, within 24 hours of you being notified of the event. These should instead be reported using the Follow-Up CRFs.

Please ensure that all (S)AEs are recorded in the patient notes, even those are defined in the CALIBRE protocol as being '**excluded**' from reporting.

Please ensure that the '**NO**', '**YES**' and '**NOT AVAILABLE**' tick boxes are completed where applicable, to avoid missing data being queried.

Every question should have a response.

The patient's 'trial number' and 'date completed' should always be entered on the front cover of the EQ5D 5L questionnaire.



5. Other News



Sadly, Abdul (Khaled) is leaving his post as Senior Trial Manager at BCTU. We thank him for his work on CALIBRE and hope that you will join us in wishing him all the very best for his future role.

Could you be our next star recruiter?

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.birmingham.ac.uk/calibretrial) or contact the CALIBRE Trial Office (calibretrial@trials.bham.ac.uk), to obtain a Practical Arrangements Form.



CALIBRE Trial Details

Sponsor:

University of Birmingham

EudraCT no.: 2018-002488-24

REC ref no.: 18/NE/0296

ISRCTN: 73887615

IRAS ref no.: 248487

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](http://www.birmingham.ac.uk/calibretrial) for trial information, training and documentation

The CALIBRE Twitter Feed for updates and discussion; Follow us [@calibretrial](https://twitter.com/calibretrial)



Chief Investigator: Prof. Dhiraj Tripathi

dhiraj.tripathi@uhb.nhs.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 both remotely and onsite, please email the above if you would like to speak to someone and a team member will call you back as soon as soon as possible.

Upcoming Trial Office Closures:

The CALIBRE Trial Office will be closed for the Bank Holiday on Monday 30th August 2021.



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

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for Health Research