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BASIL Trials Summer News!

Message from the BASIL Trials

Chief Investigator, Prof. Andrew Bradbury

BASIL-2 Update: Over 80% of our Recruitment Target Achieved!



We have passed the 300 patient landmark and recruited 314 patients to date. This means we have achieved 81% of our recruitment target! The [NIHR HTA](#) has supported remodelling the data which would mean having a sample size of 389 patients, so it's only 75 participants to go! This equates to just 4-5 participants per month which has been met over the last 12 months and is relatively easy to achieve going forward. A special thank you all of the hard working staff at site who are supporting BASIL-2.

Wishing a warm welcome to the newly opened site Karolinska, Sweden! - thank you for joining BASIL2

Currently we are preparing to submit the substantial amendment to REC to extend the follow-up to 96 months.

A team at the New England Research Institute ([NERI](#)) is joining a collaborative (with BASIL-2) whereby data will be shared with a view to pursue a meta-analysis. This meta-analysis could potentially have a significant impact on research and great scientific value.

As always, BASIL-2 trial is in capable hands of many devoted staff at individual centres. Recently a new trial manager, Tina Griffin, joined the central team at BCTU. We will be in touch to arrange meetings via teleconferences, where you would be given chance to share your positive experiences as well as difficulties and obstacles while engaging with the trial. Please direct the enquiries to usual BASIL-2 mailbox: basil-2@trials.bham.ac.uk or email t.griffin.1@bham.ac.uk

BASIL-3 Update: BASIL-3 will be resuming recruitment



"...the risk and benefits of treatment for CLTI, including drug-eluting devices, need to be examined with appropriately controlled prospective studies that are specific to the CLTI population, the execution of randomised controlled-trials involving PTX-eluting devices in CLTI...are important to the vascular community." Page 104s on the new GVG (global vascular guidelines) on the management of CLTI, June 2019. The GVG is endorsed by the BSGBI, BSIR and BSET

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After a meeting with the HTA on 4th June, BASIL-3 is going to re-open to recruitment by the end of September this year. This is supported by the [EAG report](#) for the MHRA as well as the [MHRA's MDA](#) released on the 4th June. The MHRA have stated that the use of PTX devices is still an appropriate option for patients with critical limb ischaemia.

There will be an amendment to the protocol and PIS around trial duration. As per the MHRA guidance, we have been asked by the HTA to demonstrate how we would follow up patients to 5 years—the current view is to only review mortality data at extended follow up. This is only in theory stage currently but will be included into the new version of the protocol in the event the HTA decide to fund an extended follow up.

We will be in touch with all new documentation and updates shortly. Please do not hesitate the BASIL-3 office with any comments or queries: Rebecca Record (BASIL-3 trial manager) r.record@bham.ac.uk

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