

BASIL-2 Update—HTA Meeting Result

As many of you will now be aware, the BASIL-2 Team recently met with the Director of NIHR HTA to discuss the viability and continuation of the BASIL-2 study. We have now received feedback from that meeting.

Following on from the BASIL Trials Investigators' Meeting in late 2016, recruitment to the BASIL-2 Trial has experienced a very noticeable and much needed upswing. The renewed support of this important trial means that the past four months have been our best consecutive four months for the lifetime of the trial thus far and resulted in us smashing through the 200 mark!

As a result of this much improved performance, the Director of the NIHR's HTA-programme has instructed us to keep going with the recruitment phase of the trial and it is anticipated that we will reach our total target recruitment towards the end of 2019. We hope to formalise this subsequently, provided this new momentum is maintained.

Input from the QuinteT Group

The University of Bristol's QuinteT group recently undertook a small piece of qualitative work to help understand some of the recruitment challenges associated with Basil-2. Several collaborators took part in this process, agreeing to be interviewed by a QuinteT researcher. We are grateful to those of you who took part and shared your views so openly.

Findings from the QuinteT intervention on Basil-2 indicate that there is still a commitment to the study, with several collaborators citing the lack of robust evidence base and the importance and relevance of the research question. Whilst there may be concerns about individual and MDT equipoise at different recruiting centres, there is evidently community equipoise amongst those involved in Basil-2, and this should be emphasised when discussing patient cases.

In the Basil Trials' session at the VSGBI meeting in December, there was a constructive discussion about sharing imaging across centres, and the Trial team are working on this currently. The qualitative evidence suggested that this would be a helpful way to identify, and potentially expand, the core of patients considered eligible for the study.

Previous qualitative research in trial recruitment indicates that patients find it helpful if there is a clear structure to their consultations. We have also found that it is important at each stage of the consultation to give the patient opportunity to ask questions (and to ensure that these questions are answered). Additionally, we have seen that the recruiters that are more successful are POSITIVE about the study

Patients might appreciate knowing that they are eligible to be considered for a study, and that this is based on the collective experience of the MDT. We know that it important to present balanced information about each treatment option; to explain the pros and cons of each of the treatments and to avoid loaded terminology (i.e. don't talk about 'gold standard', 'experimental' 'definitive treatment')

Finally, the QuinteT team have made some recommendations to simplify the Patient Information Leaflet, these are currently being processed.

Note: All newsletters produced by the BASIL Trial Office are controlled documents. Print and file this in the Investigator Site Folder.



Substantial Amendment 5

Since our last BASIL Trials Newsletter was published, substantial amendment 5 was implemented for BASIL-2 which includes a couple of changes which we hope will improve participant recruitment and retention. Firstly, the follow-up schedule has been slimmed down to bring the trial in-line with BASIL-3. This now means that follow-up is only due 1 month post-intervention and 6, 12, 24, and 36 months post-randomisation. "On table" randomisations are now permissible with information being given to patients and consent obtained prior to full eligibility being established. Protocol version 4.0 and PIS version 2.0 were implemented as a result of this amendment. Full details are available from the BASIL Trials Office or from the Investigators' Website.

Example BASIL-2 Angiograms

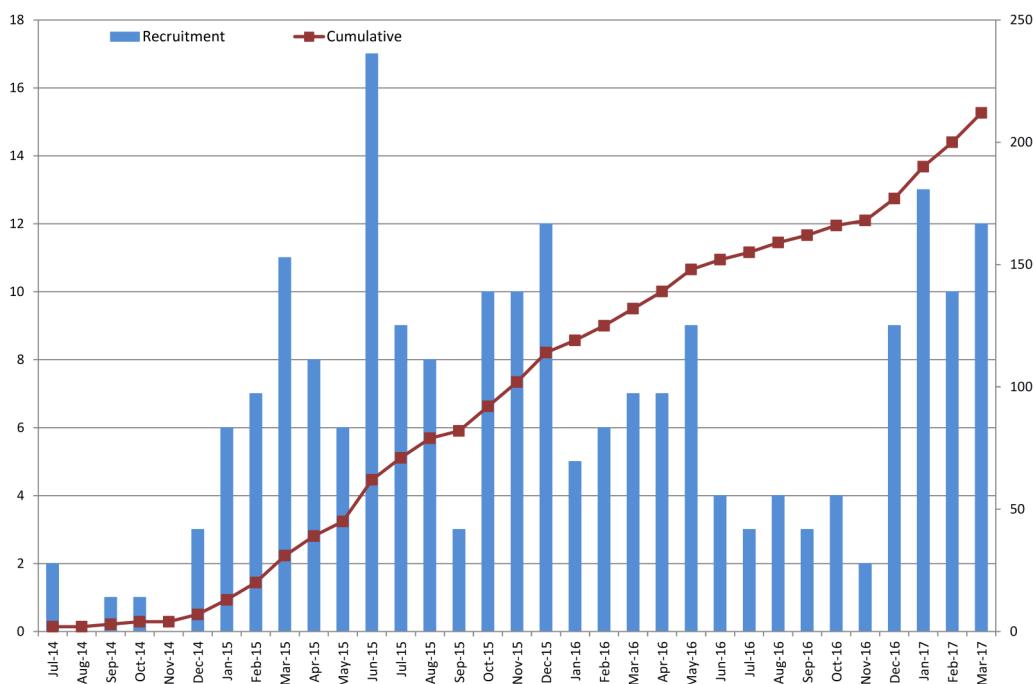
As part of our current effort in building the case for equipoise in treating SLI below the knee, we have begun publishing anonymised angiograms belonging to patients who were successfully enrolled into the trial. We hope that these will be useful in agreeing on equipoise at your MDT meetings. The current images can be found at www.birmingham.ac.uk/b2-angios.

Restaurant Voucher Scheme

The BASIL-2 Restaurant Voucher Scheme will return from April 2017. Each individual accrual to the trial will provide the randomising clinical centre with one chance in the monthly prize draw. At the end of each month, we will draw one winner to receive a £100 restaurant voucher for their efforts! Winners will be notified by email at the end of each month.



Recruitment



As of the end of March 2017, cumulative recruitment stands at 212 participants with a mean monthly recruitment over the past four months of 11 participants.

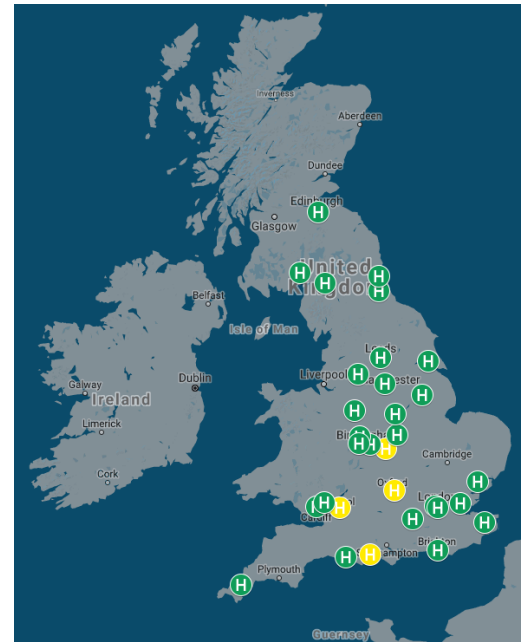
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BASIL-3 Completes its Pilot Phase!

BASIL-3 was due to begin its 12-month pilot recruitment phase in February 2016. However, due to us receiving regulatory approval ahead of schedule the first two participants were randomised in January 2016. The trial continued to perform very well throughout the remainder of the pilot with 8 of our monthly targets exceeded and another 1 met. This means that the cumulative recruitment target for the 12-month pilot was met!

We currently have 27 clinical centres open to recruitment and more to follow during year two of the recruitment phase. We anticipate opening a total of 50 clinical centres by the end of year two, placing us at full recruitment capacity for the final year of the recruitment phase.

Centres wishing to participate who are yet to express their interest should contact the BASIL Trials Office at basil-3@trials.bham.ac.uk.



Map of BASIL-3 clinical centres. Green indicates those open to recruitment and yellow indicates those likely to open in the next 30 days.

Recruitment



As of the end of March 2017, cumulative recruitment stands at 140 participants. Despite a slight slowdown in recruitment to BASIL-3 over the winter months, the trial has since exceeded its monthly target for March 2017 and we expect to see this slight cumulative deficit reduce in the coming months. As always for questions relating to patient eligibility for either of the BASIL Trials, please contact the Trials office on (0121) 415 8444 or email on basil-2@trials.bham.ac.uk / basil-3@trials.bham.ac.uk.

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