Issue 7

Summer 2016

Latest News on the BASIL-2 and BASIL-3 trials

BASIL Trials Update

BASIL Trials Newsletter

BASIL-2 Update—HTA Meeting Result

ISRCTN: 27728689

IRAS: 144764

BASIL-2 is funded by the Health Technology Programme Grant 12/35/45

ISRCTN: 14469736

IRAS: 183761

BASIL-3 is funded by the Health Technology Programme Grant 13/81/02

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

The HTA have agreed to continue to fund BASIL-2 based on us being able to demonstrate that we can recruit 15 patients per month between August 2016 and February 2017.

This rate of accrual is significantly less than our original plans and if we meet this target it is highly likely that an extension to the recruitment period will be required. If we don't manage 15 patients per month between August 2016 and February 2017 then there is a real possibility (indeed perhaps even a likelihood) that the HTA will regard the trial as non-viable and we will be instructed to stop recruitment and simply follow-up the patients already recruited by that stage

That, of course, would be hugely disappointing and a massive "missed opportunity" to answer what I think we all recognise is a very important clinical question.

A survey of BASIL-2 staff at sites was performed prior to the meeting and there were several reasons identified for low recruitment. The main reason remains difficulties with achieving equipoise in the MDTs and we urge all BASIL investigators to familiarise themselves with the slide set produced by Prof Bradbury which summarises why BASIL-2 remains relevant.

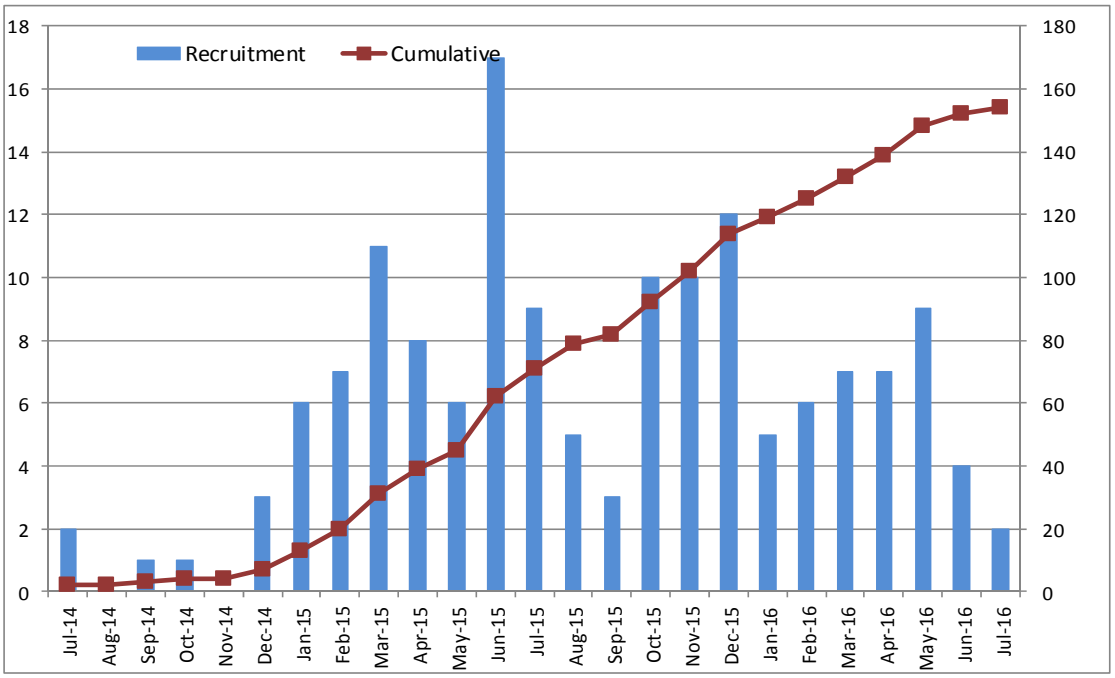
Slides are available on the BASIL-2 website (in the Investigators section –unders 'News').

To facilitate recruitment further, a substantial amendment is being produced which will bring it in alignment with BASIL-3 by:

- Permitting "on table" randomisations
- Reducing data collection, both number of timepoints and number of data items

Sites will be informed once the amendment is approved but should continue to follow protocol v3.0 until notified to do otherwise.

Recruitment



The graphic above shows how far we have to go to reach our monthly target but also shows that we have hit this level of recruitment previously when we only had around half as many centres able to recruit, so it is achievable providing all patients are being actively considered for the trial.

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

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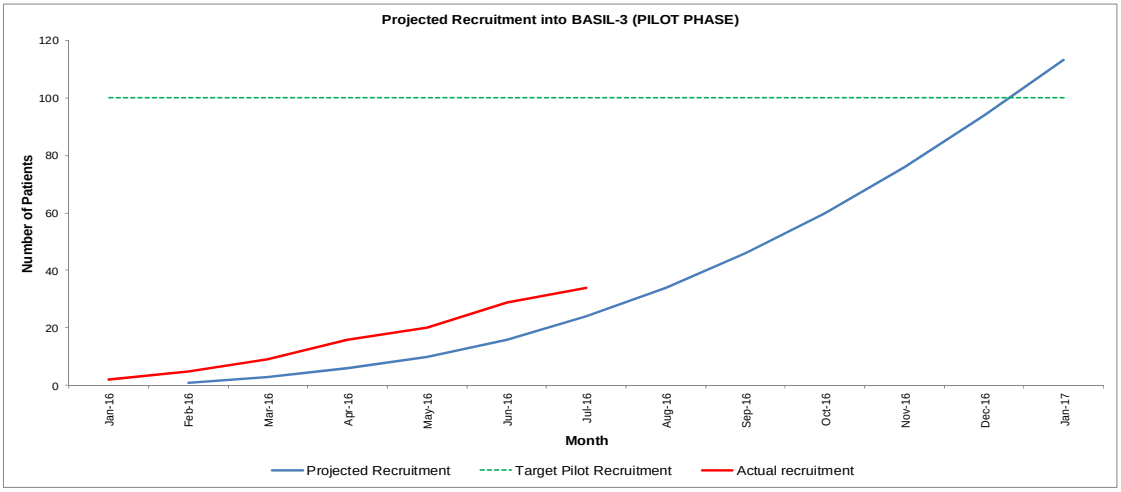
BASIL-3 Update

BASIL-3 has been open to recruitment since January 2016 and continues to perform well. There are currently ten clinical centres open and, very encouragingly, nine of these have enrolled at least one participant. Globally, 34 participants have been recruited which puts the trial slightly ahead of schedule, however, the targets set by the NIHR HTA-programme continue to increase month on month and it is imperative that we continue to open new centres in order to meet these. Bringing BASIL-3 under the jurisdiction of the Health Research Authority caused a brief hiatus in opening new sites, however we now have a good number of clinical centres at an advanced stage of start-up which will come online in the near future. In the meanwhile, we ask the ten centres that are already open to continue to consider all patients as each recruit really does count!



Questions regarding trial eligibility

During the first 6 months of BASIL-3 being open, we have received a number of questions regarding the eligibility of patients. These are summarised below:

- If a patient is randomised to drug eluting stent, for good clinical and economic reasons, the treating clinician may not want to "full metal jacket" the whole of the disease in SFA / PA with DES (or indeed a BMS). The key questions is ;"is there equipoise in respect to which treatment is best for the **index lesion or lesions** (to be defined by the responsible clinician) in the femoro-popliteal segment?". If there is, then we consider it is appropriate to randomise the patient and use the allocated treatment for the **index lesion(s).** If there are other femoro-popliteal (and/or infra-popliteal) lesions which (may) need to be treated at the same time then we consider it a matter of clinical judgement as to if, and how, they should be treated (whether by the allocated treatment or not). The only proviso is that if a patient is randomised to non-drug technology, the non-index (accessory) lesions should NOT be treated with a drug technology, and vice versa.

- It is permissible, in a patient randomised to receive a drug-eluting stent, to pre-dilate the vessel with a plain balloon prior to stenting if the responsible clinician deems this to be necessary.

- On-table randomisations to the BASIL-3 Trial are permissible provided that written informed consent has been obtained as specified in the current trial protocol.