



Issue 12
Autumn
2018

BASIL Trials Newsletter

BASIL-2 is funded by NIHR-HTA Programme Grant 12/35/45 IRAS: 144764 ISRCTN: 27728689
BASIL-3 is funded by NIHR-HTA Programme Grant 13/81/02 IRAS: 183761 ISRCTN: 14469736

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

BASIL-2 Update

Recruitment

Following on from the BASIL Trials Investigators' Meeting in June 2018, recruitment to the BASIL-2 Trial has experienced a much needed upswing, with 293 patients recruited. Thank you to all who have contributed, particularly Kolding and Royal Sussex for their notable input. The monthly recruitment target was exceeded in September which is fantastic and we hope this new momentum can be maintained. We aren't far off the next big milestone for BASIL-2 which is 300 patients and we believe we can reach this by the end of November! Thank you as always for your support.

Prizes

Congratulations to Kolding, Denmark for winning the June - August prize draw! Each patient randomised during the prize draw period entitles the site to one "ticket" into the raffle. The winner of the September - December prize draw will be revealed in the New Year. Good luck and happy recruiting!

Non-Substantial Amendment 10

NS10 was approved by the HRA on 18 October 2018 and relates to an extension of the BASIL-2 recruitment phase to 31 December 2019. All PIs and R&D departments have been notified and have until 22 November 2018 to raise an objection about the amendment. If we do not hear from you by 22 November 2018, we will assume that the amendment may be implemented at your site.

Non-Notifiable, Non-Substantial Amendment 01

A GDPR addendum to the current BASIL-2 Patient Information Sheet (PIS) (V3.0 08 June 2017) and GDPR addendum tracker were sent to BASIL-2 PIs and Research Nurses. This should be given to existing and new patients alongside the relevant PIS and documented in the patient's medical notes. Please ensure that you complete the GDPR addendum tracker and return to the BASIL Trials Office as soon as it is complete.

BASIL-3 Update

Recruitment

BASIL-3 is proceeding at a steady rate at is currently at 403 patients.

Thank you to everyone who has contributed and a special thanks to Northern General, Royal Oldham, United Lincolnshire Hospitals, and Cardiff for their renewed efforts.

Congratulations to Guy's and St. Thomas' who were the highest recruiting site between 01 June 2018 and patient 400 - your prize is on its way!



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Importance of Collecting Haemodynamic Data

Message from BASIL Chief Investigator, Professor Bradbury:

"It is crucial that we collect haemodynamic data and particularly at baseline in order that we are able to characterise our recruited patient group. Without these data, it will be difficult to generalise the results to the wider CLTI community. Please make every effort to record what haemodynamic data you can, and particularly at baseline."

ABPI and TBPI Values

The baseline and follow-up forms currently require absolute pressures to be recorded. These forms will be modified within the next CRF release so that ABPI /TBPI values may also be recorded. Prior to this release, it is permissible to write ABPI /TBPI values on the current form.

Tissue Loss and Amputations

The Trials Team often receive queries as to what constitutes "tissue loss" for the purposes of the BASIL Trials. The most common forms of tissue loss are ulcerated or gangrenous tissue which will need to be recorded for both lower limbs at baseline and subsequent follow-ups.

Minor amputation sites left to heal by secondary intention should be considered as tissue loss until such time as they are fully healed. Suture lines for closed wounds are **not** to be considered as tissue loss, but any subsequent ulceration or necrosis at these sites should be.

Please note that additional PEDIS and Wifl forms should be completed only for tissue loss occurring on the trial limb, at the level of, or below, the ankle.

Data Clarification Queries

Data Clarification Forms (DCFs) are raised in order to confirm that the data recorded on the CRF are in concordance with the trial source data. On receipt of DCFs, it is important that values are confirmed from the source data and not from your site's copy of the trial CRF.

GDPR Addendum

As a result of the new GDPR regulations which came into force in the UK on 25 May 2018, sites must provide all patients (existing and new) with a GDPR addendum. Information has been emailed to all PIs and can be found on the BASIL Trials' websites. For further information, please contact the BASIL Trials Office. It is important that we are able to track the dissemination of the addendum, therefore please return your GDPR tracker to the Trials Office when complete.



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PI Changes

Please note that PI changes must be notified to the Trials Office as soon as practical, as these need to be approved by the HRA and the sponsor, involving a non-substantial amendment and formalising the change within the site agreement respectively.

NHSmail Accounts

We are currently making efforts at the Trials Office to obtain a NHSmail inbox for receipt of trial data. Until this has been arranged, please be aware that it is possible to transfer data electronically from a NHSmail account to the Trials Office using the secure encrypt function. For further information, please contact the Trials Office.

Email Bouncebacks

We have been made aware that some emails are bouncing back when being sent to the BASIL Trials' email addresses. We have liaised with the University of Birmingham's IT department who have provided the following advice for sites:

"Contact your NHS IT departments and ask to be removed from a third party site called "dnwl.org" which filters and blacklists to check the trustworthiness of emails."

We apologise for any inconvenience caused, please contact us if you have any questions.

YouTube Channel and BASIL Investigators' Meeting

The BASIL Trials have now established their presence on YouTube! All content from the BASIL Investigators' Meeting in June are now live and can be accessed from our channel by searching for "BASIL Trials" from the YouTube homepage. Be sure to subscribe to our channel or if you'd prefer to receive the same content on a DVD then please contact the Trials Office and we will be happy to post these to you.

Contact Details

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