



BASIL-2 Inaugural Newsletter

Edition 1

Autumn2014

The Bypass versus Angioplasty in Severe Ischaemia of the Leg-2 Trial

BASIL-2 Update

ISRCTN: 27728689

IRAS: 144764

Funded by the Health Technology Programme Grant 12/35/45

Welcome

The newsletter has been created to both share progress of the trial generally, in term of recruitment etc. and to inform you of forthcoming meetings, issues that have been noted by the BASIL-2 Trial Office concerning CRF returns, and if there have been any substantial amendments or changes recently.

Newsletters will be created on a quarterly basis throughout the recruitment period of the trial and if, for any reason, a quarterly newsletter is forthcoming, sites will be provided with a note-to-file stating that a newsletter was not produced by the Sponsor for that timepoint. This edition is "Autumn 2014" and the next edition will be "Winter 2014".

Latest Progress

This section will provide a regular snapshot of recruitment per month against the projected accrual rate as well as details about the number of patients recruited per centre, per region so you can track the performance of your centre compared to that of your colleagues.

BASIL-2 is currently in early days however so for this edition only the information will not be presented graphically.

As of the 2nd September the trial was open at 3 sites, in 3 regions (Heart of England, Birmingham & West Midlands; Freeman Hospital, North-East; Southampton, South & South West) and had recruited 2 patients. The BASIL-2 Trial Office has visited 18 of the 31 sites who are currently expressing an interest in participating, covering 9 of the 11 regions.

It should be appreciated that the pilot phase of BASIL-2 is tasked with opening two thirds of the centres and recruiting 60 patients within the first 12 months. So, although there is some optimism about opening centres it is acknowledged that the recruitment of patients is going to be challenging. To give the trial the best chance of success it is vital to effectively screen patients presenting with SLI. Indeed, this data will form an important snapshot of the wider cohort against which BASIL-2 can be compared.

Forthcoming Meetings

12-14th November

British Society of Interventional Radiologists, Liverpool—publicity stand

Thursday 27th November

Vascular Society of Great Britain & Ireland AGM, Glasgow - investigator meeting at the Campanile Hotel, Picasso 2 room, 12:30-13:30. Sandwich lunch provided.

If you have not yet received an invite to the investigator meeting but would like to attend please contact BASIL-2@trials.bham.ac.uk

Regulatory History of BASIL-2 to date

3rd March 2014—original ethics approval granted pending conditions met

6th March 2014—confirmation of conditions met. Official ethical approval granted.

15th April 2014—ethical approval of 1st Substantial Amendment (primarily administrative changes but an error was corrected concerning ionising radiation)

14th August 2014—ethical approval of 2nd Substantial Amendment (including important changes to the safety reporting requirements and processing of Serious Adverse Events)

Note: All newsletters produced by BASIL-2 are controlled documents.
Print and file this in the Investigator Site Folder.