



BASIL Trials Newsletter

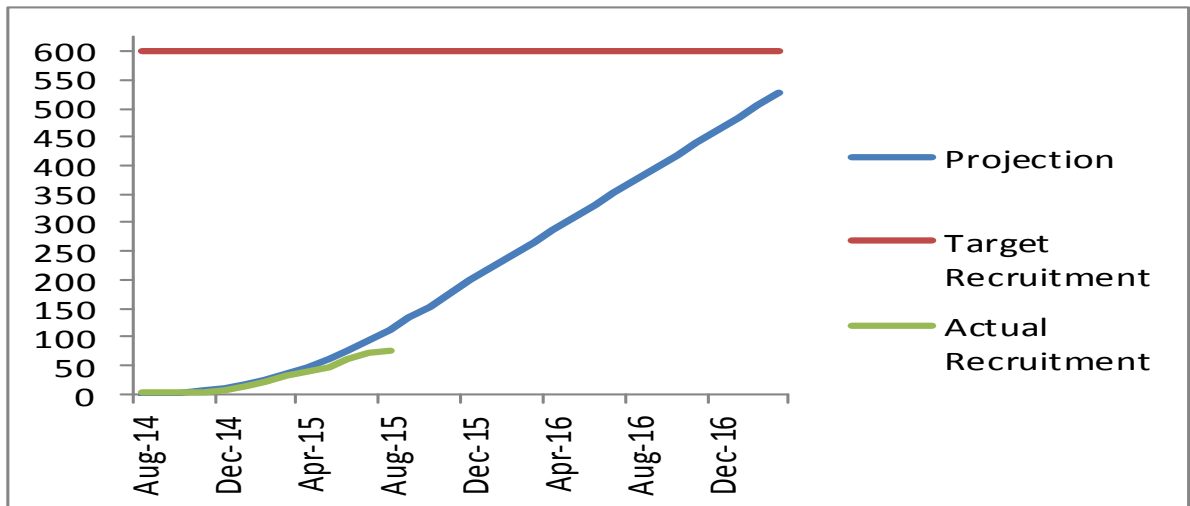
BASIL-2: Internal Pilot Recruitment Target Reached!

We are pleased to confirm that on the 16th June, we reached 50 patients. One of the criteria for the pilot phase was to recruit 60 patients in the first 12 months (modified to 50 patients in 11 months) and, thanks to all of your hard work, we have successfully met this target. June was by far our most successful month to date, with 17 patients recruited and this is the sort of level we need to maintain. Patients have now been recruited from 20 different sites, out of the 35 currently able to recruit and the change of recruitment model, below, appears to be bearing fruit.

BASIL-2: Change to the Recruitment Model and Funding

As a result of initial low accrual, the Trial Steering Committee and the funders (HTA) have backed a change of recruitment model. We are going to be opening significantly more sites, as alluded to in the last edition of the newsletter, and to more equitably reflect the contribution of all sites we are sending out Variations to Contract (VTC) to enable this to happen.

The VTCs will allow for per patient payments of £400; £200 on randomisation and £200 on final data point submission to the BASIL-2 Trials Office.



| Centre | Total |
|--------------------------------|-------|
| St Thomas' Hospital | 13 |
| Birmingham Heartlands Hospital | 8 |
| Hull Royal Infirmary | 8 |
| Royal Free Hospital | 7 |
| Leeds General Infirmary | 5 |
| Russells Hall Hospital | 5 |
| St Mary's Hospital | 4 |
| St Georges Hospital | 4 |
| Freeman Hospital | 3 |
| Manchester Royal Infirmary | 3 |
| Cumberland Infirmary | 2 |
| Frimley Park Hospital | 2 |
| Addenbrookes | 2 |
| Northern General Hospital | 2 |
| Royal Cornwall Hospital | 2 |
| Leicester Royal Infirmary | 1 |
| Northwick Park Hospital | 1 |
| Royal Gwent Hospital | 1 |
| Southampton General Hospital | 1 |
| Worcestershire Royal Hospital | 1 |
| | 75 |

BASIL-2 Monthly Recruitment

As of the 13th August the trial was open at 35 sites, in 11 regions and had recruited 75 patients. Well done to St Thomas Hospital who are the number 1 recruiting centre at the moment.

As well as the sites shown adjacent, there are another 15 sites which are currently able to recruit but have yet to do so. It would be great if we could get some of these on board as it only requires small numbers from each site to make a big difference to the overall accrual rate.

Next Target: 120 patients by September 30th

BASIL-3: Submitted to Ethics!

We are delighted to report that the BASIL-3 Trial documentation was sent for ethical approval at the end of July and we are awaiting response to our “responses to comments”.

BASIL-3 will be a 3-armed trial looking at purely endovascular interventions; plain balloon with or without a bare metal stent (+/- BMS) v drug coated balloon +/- BMS v drug eluting stent.

We anticipate sending out feasibility forms for the trial imminently.

WATCH THIS SPACE!

BASIL-2: Telephone Follow-ups

We strive for 100% complete data collection but recognise that some patients randomised into BASIL-2 live considerable distances from their base hospital and that it might be difficult for these patients to attend the hospital for the scheduled Trial follow-up visits.

If you are unable to conduct face-to-face follow up visits with your patients it should be possible to obtain the majority of the data required by telephone and letter. The ‘Follow-up Form’ (with the exception of the haemodynamic data), ‘Healthcare Use Form’ and ‘Personal Circumstances Form’ (the latter two being at the end of the HRQoL booklet) can all be completed by talking to the patient and/or a relative on the telephone.

The HRQoL booklet can be posted out to the patient along with a stamped addressed envelope and then checked for completeness by the Research Nurse when it is returned. Any questions that may have been missed can then be completed by telephoning the patient. The ‘PEDIS’ and ‘WIFI’ tools (if required) might be completed by speaking to the patient’s district or practice nurses on the telephone to enquire as to the progress of foot ulcers or minor amputation wounds (although we recognise that it might not be possible to obtain the ‘Ischaemic Status’ data for WIFI).

BASIL-2: HRQoL for Bilateral Amputees

Patients randomised into the BASIL-2 Trial should remain in follow up even if they undergo a major amputation (ie above the ankle) of their trial leg. Occasionally patients may have bilateral major leg amputations and, in these cases, it is clearly inappropriate to ask them to complete the VascuQoL questionnaire. If this scenario arises for any of your patients we ask that you simply remove the VascuQoL pages from the HRQoL booklet, administer the remaining HRQoL tools as normal and make note of the fact that VascuQoL has not been administered on the front of the booklet.

BASIL Trials: Forthcoming Meetings

4-6th November: British Society of Interventional Radiologists, Glasgow —publicity stand + presence during drinks reception on Wednesday 4th, 18:15-18:45

11-13th November: Vascular Society of Great Britain & Ireland Annual Scientific Meeting—publicity stand + investigator meeting in the Bourne Suite, BICC from 12:30-13:30 on Thursday 12. Sandwich lunch provided.

PLEASE INFORM THE BASIL OFFICE IF YOU WISH TO ATTEND EITHER SESSION

Basil-2: Data Quality

With recruitment on an upward trajectory, we are now looking at the quality of data we're receiving back. All outstanding CRF data queries will be sent out to sites via email on a regular basis hereon in. Wherever possible please refer back to the original paper CRF referred to in the query, correct any mistakes or missing information, initial and date this change, take a photocopy and send this to the Basil 2 trial office. We will regularly be offering you helpful advice on the newsletters and via email to make completing CRFs easier and reducing the number of queries.

Basil-2: Data Quality Tips and Tricks

Patient Identifiers: Please ensure the Unique Basil-2 Trial number, the Patients initials and date of birth are on the top of each CRF form.

Form sign off: Check the 'completed by' section is completed on each and every CRF form. CRFs MUST be been completed by members of staff who are on the delegation log.

Clinical Source Data: Always ensure you take a copy of the completed CRF and file one copy at your site sending the other to the Basil-2 trials Office.

Tick Boxes: All questions require a response. Yes/No questions cannot be left blank. In certain circumstances you can write the reason why certain measurements or questions have not been answered on the CRF but please initial and date any annotations you do make.

Examples

| | |
|--|--|
| Was the surgery combined with amputation? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If yes, please complete an Amputation Form | |
| Post-bypass surgery pulses (to be assessed and recorded during the 24hrs following the bypass surgery) | |
| Tick each pulse that is palpable Popliteal: <input type="checkbox"/> No <input type="checkbox"/> Yes DP: <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes PT: <input type="checkbox"/> No <input type="checkbox"/> Yes | |
| Post-bypass surgery pressures (to be measured and recorded during the 24hrs following the bypass surgery) | |
| Right Brachial BP: <u>162/</u> mmHg | Left Brachial BP: <u>150/</u> mmHg |
| Right Leg: NF = not found, NC = not compressible | Left leg: NF = not found, NC = not compressible |
| DP: <u>86</u> mmHg <input type="checkbox"/> NF <input type="checkbox"/> NC | DP: <u> </u> mmHg <input type="checkbox"/> NF <input type="checkbox"/> NC |
| PT: <u>50</u> mmHg <input type="checkbox"/> NF <input type="checkbox"/> NC | PT: <u> </u> mmHg <input type="checkbox"/> NF <input type="checkbox"/> NC |
| PP: <u> </u> mmHg <input checked="" type="checkbox"/> NF <input type="checkbox"/> NC | PP: <u> </u> mmHg <input type="checkbox"/> NF <input type="checkbox"/> NC |
| Hallux: <u> </u> mmHg <input type="checkbox"/> NF | Hallux: <u> </u> mmHg <input type="checkbox"/> NF |

Post-bypass surgery pulses: DP has been ticked 'Yes' however 'Popliteal' and 'PT' has been left unanswered. To prevent queries being raised, tick 'Yes' or 'No' in the tick boxes next to 'Popliteal' and 'PT'.

Post-Bypass surgery pressures: the left Brachial BP has been provided, but no other data or clarification for the missing data is provided. An appropriate response would be to provide details if possible, tick 'NF' or 'NC' where appropriate or add a note for the reason this was not done, for example "N/A Left leg has had an Amputation".

Endovascular Summary and Segment Forms: Please ensure that the number of items ticked yes in the treatment section of the summary form corresponds to the number of Endovascular Segmental Treatment Forms returned.

Smoking Status: The standard way to record this data is in "pack years". You need 2 pieces of information to achieve this: the number smoked per day and the number of years smoked. 20 per day for 1 year = 1 pack year

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