



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

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BASIL Trials Newsletter

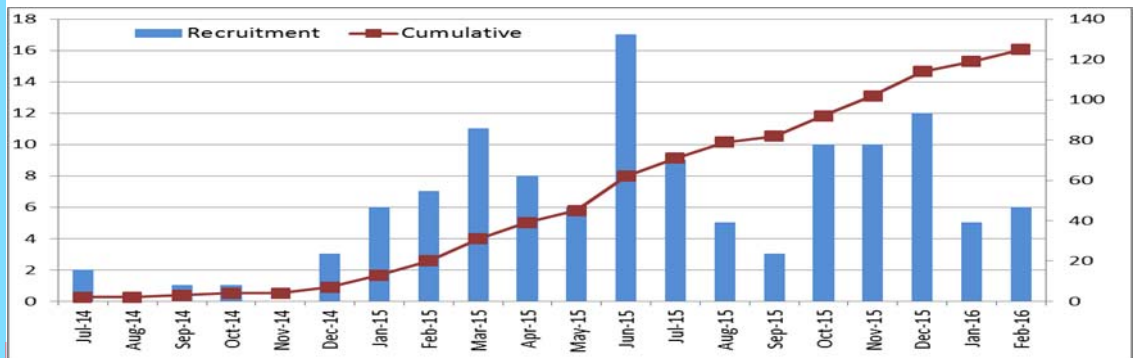
BASIL-3: Open to Recruitment!

We are delighted to announce that BASIL-3 opened its first site (Cumberland Infirmary) to recruitment on 12th January! Since then, we have welcomed The Royal Cornwall, Heart of England, and Northern General. To date (2 March), we have randomised a total of five patients from two of our centres with the other two centres working hard to identify their first participants. We are positively encouraging new sites to join and anticipate having around 60 centres, in total. BASIL-3 has its own website and many of the trial documents can be found here <http://www.birmingham.ac.uk/Basil-3>

With a new trial comes a new Trial Coordinator, in the form of Benjamin Hunt. Benjamin comes with previous experience in trial co-ordination and has experience in overlapping diseases. He will be the first point of contact for all matters relating to BASIL-3, going forward, but advise you to use the generic email address BASIL-3@trials.bham.ac.uk

BASIL-2: Recruitment Update

As of 14th March 2016 the trial was open at 46 sites and had recruited 131 patients. Although the number of patients recruited during the last quarter were not too far adrift from the new targets set by the HTA (recruited: 10, 10, 12; target: 12, 14, 16), January and February have proved a salutary reminder that all centres need to keep searching for these patients, as only 5 were recruited in January and 6 in February; our target were 18 and 20. The next Monitoring Visit with the Director of the HTA will take place sometime in May 2016 (date to be confirmed). In order to satisfy the requirements set out by the Director at our last Monitoring Visit in September 2015 we need have around 200 patients randomised by the time we meet him again. This means we need to randomise 70 patients in the next two months. Given that we have almost 50 BASIL-2 centres currently open across the UK, we are hopeful that this can be achieved. If, by the time we meet the Director in May we are around the 200 mark then we feel it is likely that BASIL-2 will be removed from close monitoring and that the financial future of the trial should be secure. If, however, we are far short of 200 then the trial will remain at risk. If each centre could randomise just one patient per month between now and May we would comfortably exceed the target and the future of BASIL-2 would be secure. **Please keep a lookout for suitable patients; every single patient counts at this vital stage of the trial's life - thank you!**



BASIL-2: Protocol Amendment

This is advance notification that substantial amendment 04, for BASIL-2, was approved by Ethics on 26th January, 2016. Central R&D checks have been delayed but this amendment will be coming through imminently.

BASIL-2: Recruitment by Centre

St Thomas' Hospital	19	Addenbrookes	2
Birmingham Heartlands Hospital	14	Royal Cornwall Hospital	2
Hull Royal Infirmary	14	Leicester Royal Infirmary	2
Leeds General Infirmary	13	Royal Oldham	2
Russell's Hall Hospital	8	Pilgrim Hospital	2
Royal Free Hospital	8	Ninewells Hospital	2
St George's Hospital	5	Northwick Park Hospital	1
Freeman Hospital	5	Worcestershire Royal Hospital	1
Manchester Royal Infirmary	5	Kent & Canterbury	1
Royal Gwent Hospital	5	Oxford (John Radcliffe)	1
St Mary's Hospital	4	Southampton	1
Sheffield	3	Royal Bournemouth	1
Cumberland Infirmary	3	Colchester	1
Queen Elizabeth, Glasgow	3	Walsgrave	1
Frimley Park	2		
Grand Total			125

BASIL Trials: Changes to Eligibility Criteria

Although most centres will have only recently received the BASIL-3 protocol, it has been necessary to amend it in the light of developments with BASIL-2 and changing practice across the UK. Of particular interest to centres will be the ability to randomise patients who are having a pre-planned "hybrid" procedure. Originally, it had been the intention not to permit "hybrid" procedures in BASIL 2 or 3 but in order to remain relevant they have to adapt pragmatically to changing practice. With more centres having dedicated hybrid units, this change to the eligibility was endorsed by the BASIL-2 TSC and has been incorporated into the forthcoming amendment for BASIL-3 which is currently undergoing the review process.

BASIL Trials: Per Patient Payments Boost

Following a review of the models for recruitment for both trials we are pleased to announce a doubling of the amount paid per patient on recruitment. BASIL-2 has been operating on the basis of £400 per patient, in total, since the summer of last year; £200 on randomisation and £200 on final data point for the patient. At the Trial Steering Committee meeting in November it was decided to double the initial payment to £400 on recruitment, whilst maintaining the £200 on final data point.

All centres will shortly be receiving variations to contract for BASIL-2 to reflect this change, and the effective date will be from January 1st, 2016, so all patients recruited so far this year will be paid at this increased rate.

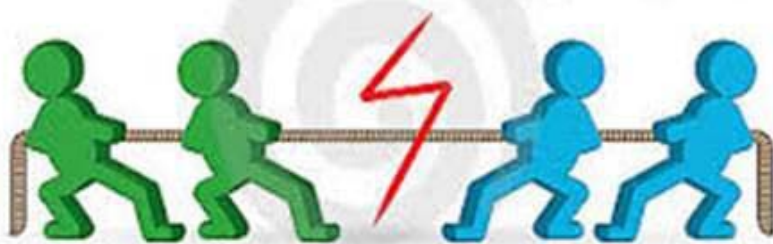
For simplicity and equanimity, BASIL-3 will operate the same per patient payment mechanism. For those sites who have only recently signed contracts agreeing to £400 per patient, rest assured that the effective date will again be back-dated, so you won't be losing out by randomising patients in the meantime.

COMPETITION EXTENDED: Win Restaurant Vouchers!

The use of restaurant vouchers to incentivise recruitment has been deemed a success and therefore we intend to keep the competition going until further notice.

Each time a recruiting centre recruits a patient to BASIL-2 they will get an entry into the monthly draw for £100 of restaurant vouchers of your choice to be shared by the winning team. The more patients you randomise in a calendar month, the more entries you get into the draw.

COMPETITION



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