



Planet-2 Autumn Newsletter

Issue No 9
November 2013

Editorial

Welcome to the newest edition of the Planet-2 Newsletter.

The great news is that 141 babies have now been randomised which means that we are nearly 1/4 of the way to our target figure. The Manchester team have had a brilliant month, randomising 4 babies in October out of the 11 they have recruited since they started in March this year. Congratulations also to Bradford Royal Infirmary who randomised their first baby this month. The N Ireland network are also doing well and have now randomised 4 babies. All this activity means that we reached our target in October by recruiting 11 babies

Thanks to everyone for all the hard work.

There are a couple of important trial issues covered in this newsletter, so please do take the time to read through it. The need for a pre – randomisation scan is discussed, and there is an article introducing a new core member of the team, Julie May, to the study

St George's, London, are just about to join the trial and we have other new centres coming on board soon, including our first overseas centres in the new year. The team are quietly optimistic that the recruitment rate will really start to pick up.

Simon Stanworth, joint CI, is offering champagne / chocolates for the team randomising No 150, so Good Luck to everyone!

News in Brief:

- The number of babies randomised to Planet has now reached 141
- Welcome to new staff and centres joining the trial
- Next TMG T/C is Mon 11th Nov, 11.00-13.00
- Next PI T/C is Weds 27th Nov 12.00-13.00.
- Research Nurse T/C is Tues 3rd Dec, 10.00 - 11.00
- TSC T/C is Mon 13th Jan 2014, 14.00—16.00

All dial-in details will be sent out, or contact Karen.

We are intending to run a day for Planet-2 Investigators in February. The venue will be central London. Details will be announced as soon as confirmed

Meet the Northern Ireland network nurses - Judith Ratcliffe

Within Planet-2 the NI network nurses cover four major recruiting hospitals and also continuing care sites. To date four babies have been randomised (which we are all very excited about) – with one of these babies transferring between sites without any loss of data collection. Other babies have been consented but their platelet levels have not fallen below 50 and some babies' platelet levels that have fallen were born after 34 weeks gestation . Babies are screened daily to ensure that all eligible babies are approached .

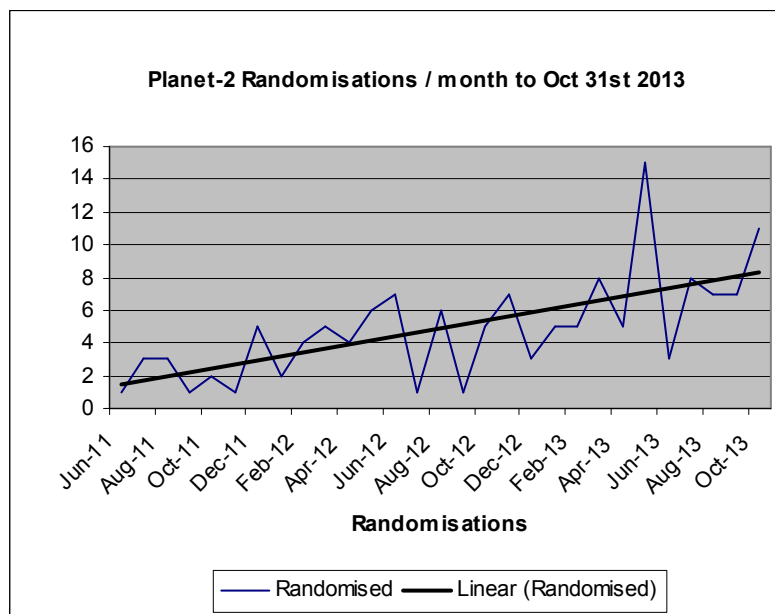
Other research studies that we are recruiting to are Eczema And Food Allergy, PREDNOS, ITP Registry, SANAD II and APTS .



L-R Research Nurses; Judith Ratcliffe, Sara Gilpin, Julie Brown, Muriel Millar . (Not pictured is Patricia McCreesh)

Randomisations and Rate to 31st Oct 2013

Sites	Total No Enrolled since opening	No Randomised 2013	Monthly Randomisation Rate this year
St Mary's, Manchester * (opened March 2013)	11	11 (since March)	1.4
Royal Bolton Hospital	9	9	0.9
St Thomas's, London	25	8	0.8
Addenbrooke's, Cambridge	25	8	0.8
Royal Victoria Infirmary, Newcastle	7	6	0.6
John Radcliffe, Oxford	13	5	0.5
N Ireland network	4	4	0.4
Royal Gwent Hospital	4	4	0.4
Norfolk & Norwich	14	3	0.3
Imperial	8	3	0.3
James Cook, Middlesbrough	3	3	0.3
University Hospital of Wales, Cardiff	6	2	0.2
Royal Cornwall, Truro	2	2	0.2
Queen Alexandra, Portsmouth	4	1	0.1
Univ. Hospital of North Tees,	2	1	0.1
Royal Preston Hospital	1	1	0.1
Luton & Dunstable	1	1	0.1
New Cross, Wolverhampton	1	1	0.1
Bradford Royal Infirmary	1	1	0.1
Cork University Maternity Hosp	0	0	n/a
Sunderland Royal	0	0	n/a
Royal Berks, Reading	0	0	n/a
TOTAL	141	74	



Trial Matters

Pre - Randomisation Scans

During monitoring visits and also following review of the CRFs, we have found that a number of pre-randomisation scans have not been performed within the requisite 6 hours, and this constitutes a breach of the protocol.

The pre-randomisation USS scan is mandatory and is in place as an important safety measure - it is essen-

tial that babies are scanned and found not to be actively bleeding before they are randomised. On the randomisation website it is necessary to click a button to confirm the scan has been undertaken before randomisation can proceed, but in some cases this has been clicked without checking the scan status.

The danger is that an actively bleed-

ing baby will be randomised to the lower arm and this could constitute a risk of harm to the baby. Can you please remind all clinicians of the necessity to perform this scan, which brings us on to ...



Training Logs

The importance of maintaining a comprehensive training log was brought home at a recent Ethics & GCP Forum. Training logs are essential documents in the running of a research trial, and are often one of the first documents checked by monitors, including those conducted by the regulatory agencies.

A training log demonstrates that those taking part in the study are trained in various aspects of the trial, and should cover anyone on the dele-

gation log. This includes attendance at the site set-up presentation, when an attendance list is taken and can be cross-referenced to demonstrate training. However, as new trainees etc participate in the trial, it is important that there is evidence of training in the protocol before undertaking such tasks as seeking informed consent. The training can be conducted on an informal 1:1 basis by the research nurse or PI, & I know many of you are continually updating the

training of fellow research team members. However, please remember to document these occasions.

If there has been a protocol breach, it is essential that this is addressed by refresher training, and if this is logged it provides evidence that the issue is being managed to prevent recurrence.

28 day scan

In order to achieve one of the primary outcome measures for Planet-2, a **cranial USS at SD 28 is ESSENTIAL**. This can be performed +/- 3 days. There have been some CRFs transmitted without this information, which means we can not analyse the data to the standard we would like.



We have been considering how to ensure this scan is performed and recorded on the CRF.

To improve this data, Julie May (see below for more details) or Karen will be sending out emails to sites around 28 days post-randomisation as a reminder to undertake a cranial USS

Introducing Julie May ...



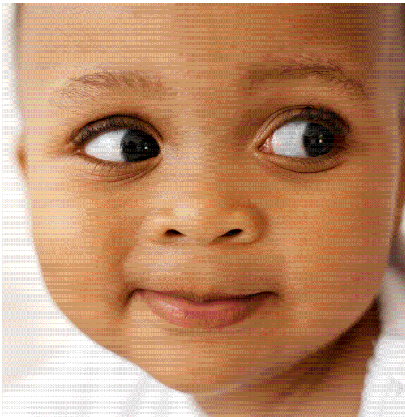
My name is Julie May, I have recently joined the PlaNet 2 team as a research nurse. I will be helping to coordinate the 2 year neurodevelopment follow up and outcome for the study. I have also undertaken the Bayley 3 assessment course and will be assessing our babies here at Addenbrooke's.

My email address is julie.may1@addenbrookes.nhs.uk

A little bit about me; I am married, have a son and 2 dogs.

I worked as the Lead nurse for the Neonatal community team here at Addenbrooke's until 2 years ago when I then went to work for the Department of Paediatrics as a research nurse. I am looking forward to joining the Planet team and hoping to meet you all over the next few months.

Consenting



On the whole the consent rate to the trial is very good, with the average rate about 60%. However, some PIs feel that they could benefit from more guidance as to how to approach parents / guardians for consent. Anna Curley, joint Chief Investigator, has drafted a suggested 'script' to help those seeking informed consent to Planet-2. Anna and the team at Addenbrooke's have been in the trial since June 2011 and have used a variety of approaches for taking consent. They feel that the lessons they have learnt may be beneficial to other sites.

The document has now been sent around the Trial Management Group for review, and will shortly be distributed to all sites.

Transmitting CRF data

Renate Hodge, Planet-2 data manager, is in the process of reviewing CRFs transmitted to the NHSBT. Much of the data is of a high quality, so thank you for your conscientious work.

We are now trying to streamline the data collection & input process, so could everyone please send CRFs over as soon as possible after completion (ie Study Day 28 and End of Study. Safety reports to be sent asap). This will enable Renate to send out queries in a more timely manner, and it will probably be easier to answer any data queries at that stage.

In return we will endeavor to generate the queries much more quickly from here once the CRFs have been received.



And Finally

Don't forget:

- **Champagne or chocolates at No 150** (now only 8 more to go!)
- The Planet-2 Investigator Day - Date and venue to be announced
- More mugs coming soon!!

