



Planet-2 Newsletter

Issue 6
March 2013

Editorial

Welcome to this new bumper, 4-page edition of the Planet-2 Newsletter. Since the last edition in January, fifteen babies have been recruited to the trial, which is fantastic news. You will see from the table and graph on page 2 that the rate of recruitment is definitely on the rise, and reflects both the increased numbers of sites involved and the hard work you are all contributing when screening, consenting and enrolling babies.

We appreciate that these babies are relatively rare, so I know that a great deal of hard work goes on in the background of the trial that is not necessarily recognised in the numbers. However, even the data from the screening logs

is analysed and proving to be useful in providing background information for the trial

In this edition Morag Zelisko from Royal Berkshire Hospital has contributed an article on the team at Reading, and Sara Barnett from Imperial has written a piece on the recent NIHR MCRN Neonatal Network Meeting

If you want me to include any of your articles or want some more detail on a particular aspect of the trial featured in the next edition in May, please get in touch

Best Wishes
Karen

News in Brief:

- **The number of babies randomised to Planet has now reached 83**
- **Welcome to new staff and centres joining the trial**
- **Next Research Nurse telecon is 10.00-11.00 on Weds 27th March**
- **Next PI telecon is Weds 3rd April 12.00-13.00.**

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

Meet the Planet-2 Team at Royal Berkshire



Morag Zelisko, Nicky Pritchard & Sue Hallett

The Royal Berkshire Hospital is a very large general hospital foundation trust in the Thames Valley with collaborative links with Oxford, Southampton and London. Research and Development is high profile with a Consultant R&D lead. Neonatal based research projects have grown and progressed within the last 2 years from neonates, diabetes and into paediatrics

We are currently involved in Planet2, (screening daily but smiles turn to frowns with rebounding platelet counts) Prednos, ICISS, WAIT, POPS, PIPS, (no typos!) I2S2 (Bayley's Assessment) UKALL11. We are embarking shortly on European survey, with a few other studies up our sleeve and always happy to consider more

The enthusiastic Planet2 team includes PI Nicky Pritchard, Paediatric Consultant, Research Nurses Sue Hallett and Morag Zelisko (0.5WTE), both specialised in Neonatal intensive/Special Care and Paediatrics. Sue also works with the adult generic team and as Team Leader.

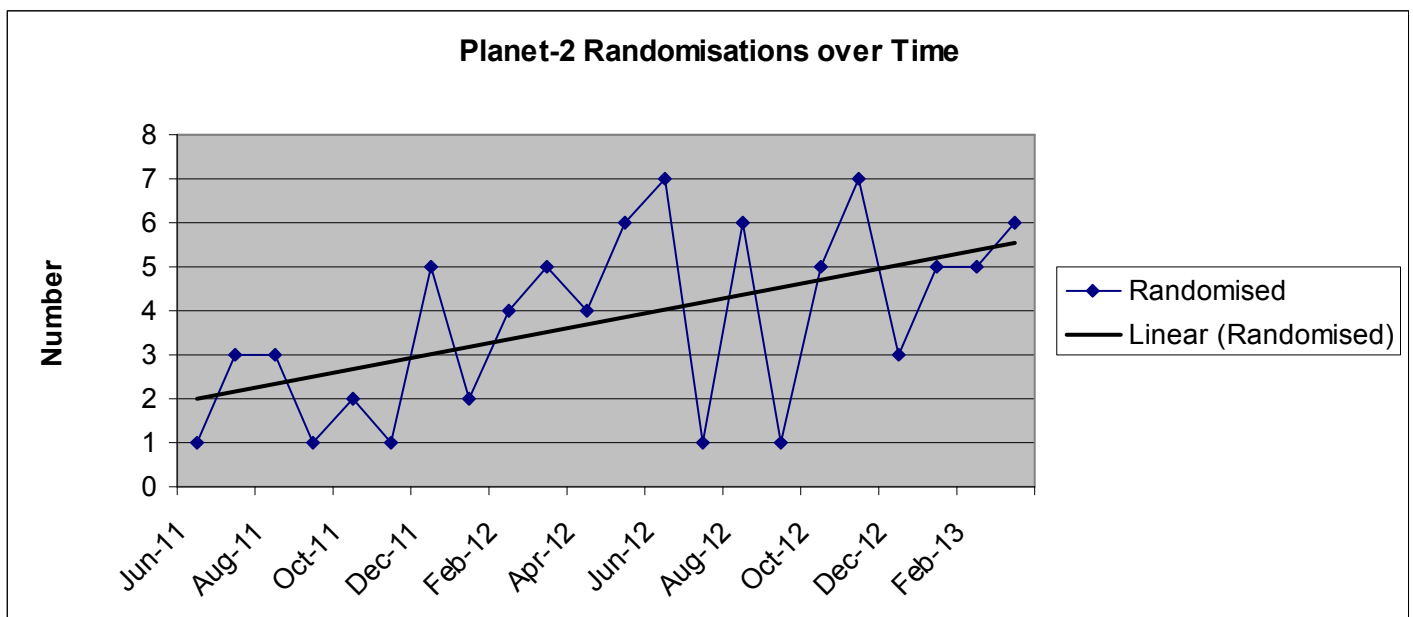
Our contact details are: child.research@royalberkshire.nhs.uk 0118 322 8652 and are always open to sharing ideas. Good luck to everyone on Planet2

Contact Planet-2 Trial Manager: Karen Willoughby. Email: kw369@medschl.cam.ac.uk

Planet-2 Enrolment to Mid March 2013

Sites	Total No enrolled	First patient randomised
Addenbrooke's, Cambridge	18	13 Jun 2011
St Thomas's, London	19	16 Jul 2011
Norfolk & Norwich	12	30 Dec 2011
John Radcliffe, Oxford	9	17 Oct 2011
Imperial	7	16 Jun 2012
Queen Alexandra, Portsmouth	4	21 Jun 2012
Univ. Hospital of North Tees,	2	16 Sep 2012
Royal Berks, Reading	0	n/a
Luton & Dunstable	0	n/a
James Cook, Middlesbrough	1	22 Jan 2013
Royal Bolton Hospital	3	01 Jan 2013
Bradford Royal Infirmary	0	n/a
University Hospital of Wales, Cardiff	5	13 Oct 2012
Royal Preston Hospital	0	n/a
Royal Victoria Infirmary, Newcastle	1	23 Dec 2012
Cork University Maternity Hosp	0	n/a
N Ireland network	0	n/a
Royal Cornwall, Truro	0	n/a
New Cross, Wolverhampton	0	n/a
Royal Gwent Hospital	2	16 Jan 2013
TOTAL	83	

Although there are relatively large monthly variations in numbers randomised to the trial, the trend is clearly upwards as you can see from the graph below



Here are answers to some of the most frequently asked Planet queries:

- ***Can I enrol a baby that has had a pre-randomisation platelet transfusion?***

If a baby has a platelet transfusion prior to randomisation, it is not excluded from Planet recruitment. Check the last platelet count, and if it is below 50 you can still randomise, or wait for it to drop.

- ***Can a baby be consented to the trial if the count has climbed back above 100?***

If a platelet count has dropped below 100, and then recovers either spontaneously or following a transfusion, the baby can still be consented. The consent is therefore in place if required quickly for randomisation later if platelets drop below 50.

- ***What if a count drops below 50 and there is no one around to perform a pre-randomisation cranial USS if one hasn't been undertaken within the last 6 hours?***

If a count drops below 50 and it is difficult to get a pre-randomisation cranial ultrasound scan performed at that time, there is no time limit from receiving the platelet count to undertaking the scan. Therefore, if the latest count is below 50 you can scan when more staff are available in the morning and then randomise provided all the other criteria are met.

- ***Is there any restriction on postnatal age at enrolment?***

A baby can be recruited to the study up to 38 weeks CGA provided they were born below 34 weeks CGA. The only proviso is that there must be an expectation that we can gather 28 days' worth of data to achieve the primary outcome

- ***As the recruitment window can be small, how can we maximise enrolment?***

To get best recruitment, consent & randomisation rates it is helpful to have cover ideally in place 24 / 7. Therefore, having a good number of personnel able to perform these functions on the delegation log really helps

New Training Presentation

~ *By popular demand*

We are reviewing the training presentation with the intention of uploading a new one on to the website for Planet refresher courses at participating sites. I'll let you know when it's uploaded



NIHR MCRN Neonatal Network Meeting

23 January 2013 Birmingham ~ Sara Barnett Research Midwife Imperial College

The aim of the MCRN Neonatal Network is to link neonatal units to research that addresses important issues in the provision of neonatal care

Members of the Planet-2 team were well represented at the latest meeting. It was of great value to meet in person to share experiences and to hear of other research projects conducted nationally. We also heard of issues faced by other research projects some of which were familiar, others not yet encountered.

The breadth and numbers of studies conducted nationally was of great interest¹. Highlighted as a national research challenge are the amount of babies to be recruited to new studies n 2500^{2,3} and the challenge facing researchers of recruiting babies and their families to multiple studies in the same unit.

jon.doriling@nottingham.ac.uk

(cont p4)

Contact Planet-2 Trial Manager: Karen Willoughby. Email: kw369@medschl.cam.ac.uk

The importance of all research nurses and doctors attending Good Clinical Practice updates was discussed and the difficulties of persuading colleagues to attend was widely acknowledged despite this being a prerequisite for signatures on a delegation log⁴.

The wider responsibilities of coordinating trials were discussed by Claire Snowden from the London School of Hygiene & Tropical Medicine. The priority a research trial takes in a parent's journey on a NICU was sensitively tracked from being very much in the foreground at consent and recruiting, to moving into the background as the trial proceeds and other issues become important, then disappearing off the parent's list of priorities as the baby prepares for discharge.

Priority setting was explored tracking a PhD student's project on gathering research and parental experiences of pre-term birth. The James Lind Alliance⁵ is for "tackling treatment uncertainties together". Patient/carer organisations and clinician organisations work together to confront uncertainties about the effects of treatments in their area of interest. They may also, if appropriate, address other issues such as diagnosis and aetiology. The themes uncovered for further investigation were those highlighted by parents of pre term babies⁶.

Partnerships between parents and nurses in research was movingly explored by Zoe Chivers representing Bliss⁷ and acting as the parent's advocate on the NICU. Throughout the day Zoe called for the views and needs of parents to be paramount in research considerations. She called for research to be "*with or by parents* , not *to, about or for*"

New definitions in prematurity and the challenges of following up babies assessing morbidity and the health care needs of babies enrolled in research trials was presented by Elaine Boyle from Leicester. Smaller seminar groups based on the subjects presented were facilitated allowing views to be exchanged and the atmosphere was informal , supportive and conducive to honest discussion. Future multidisciplinary updates and study days (especially if free !) are most welcome.

References

1. <https://www.npeu.ox.ac.uk/trials>
2. sift@npeu.ox.ac.uk
3. elfin@npeu.ox.ac.uk
4. <http://www.crncc.nihr.ac.uk/NR/exeres/B0A499AD-6F5C-4ECC-A726-41E528D18B7C>
5. <http://www.lindalliance.org/Introduction.asp>
6. <http://www.library.nhs.uk/duets/>
7. <http://www.bliss.org.uk>

Once again, thanks for all your hard work on Planet.

Contributions to the next newsletter gratefully received!

Hope to speak to you at the next teleconferences.

***Best Wishes
Karen***