



## PlaNeT-2

## Autumn Newsletter

Issue No 11

### Editorial

Welcome to the latest edition of the Newsletter. It has been a busy period for PlaNeT-2 since the last edition back in April. The fantastic news is that the randomisation rate has really improved recently, and October has been the best month for randomisations so far, with 18 babies joining the study. In fact the last 3 months have produced some of the best randomisation figures for the entire study. Sixteen babies were randomised in August & 15 in September. The team are confident that the half way figure of 330 will be reached by end February 2015!

We achieved the landmark figure of 250 babies randomised to the trial in the late summer. James Cook randomised the milestone baby and won 2 bottles of champagne, which I believe they are offering in turn as a prize for a PlaNeT-2 quiz on the unit. Amanda and Suzanne wrote a short article about the unit below.

The Dutch sites have also been a wonderful addition to the trial, and you can see from the league table on p 2 that they have been randomising reliably and steadily since each unit opened. We have a photo of some of the team in the Netherlands, and hopefully we will have more information on the Dutch units in the next edition

Just as welcome is the reappearance of some of the older units randomising to the study again. Once again, it demonstrates the importance of perseverance with screening. **St Thomas' in particular have had an amazing couple of months, randomising 11 babies since July!**

A couple of major events have also occurred with PlaNeT since April; the research nurse study day, and the substantial amendment. There is more information on both of these in the newsletter.

Thanks for all your hard work

*Best Wishes, Karen*

### News in Brief:

- The number of babies randomised to Planet is now 288
- Next TMG face to face: TBC
- Next PI T/C is Tues Nov 25th Time TBC
- Research Nurse T/C Nov 5th at 10.00
- TSC face to face 16th Dec, 13.00—16.00

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

### Meet the Teams

#### James Cook—prize winners for Baby No 250

We are a busy level 3 unit with 8 ITU, 6 HDU & 16 SCBU cots. We both work research and clinical shifts on the neonatal units and are very well supported by the medical and nursing team



Helen Chitty (Research Fellow),  
Mithlesh Lal (Consultant Neonatologist & PI),  
Amanda Savage & Suzanne Bell (Research Nurses)

#### Amsterdam Medical Centre

Here are the team from AMC who are doing so well with recruitment: (L to R): Wes Onland, neonatologist,  
Debbie Nuytemans, clinical research coordinator, department of neonatology  
Anton van Kaam, professor in neonatology



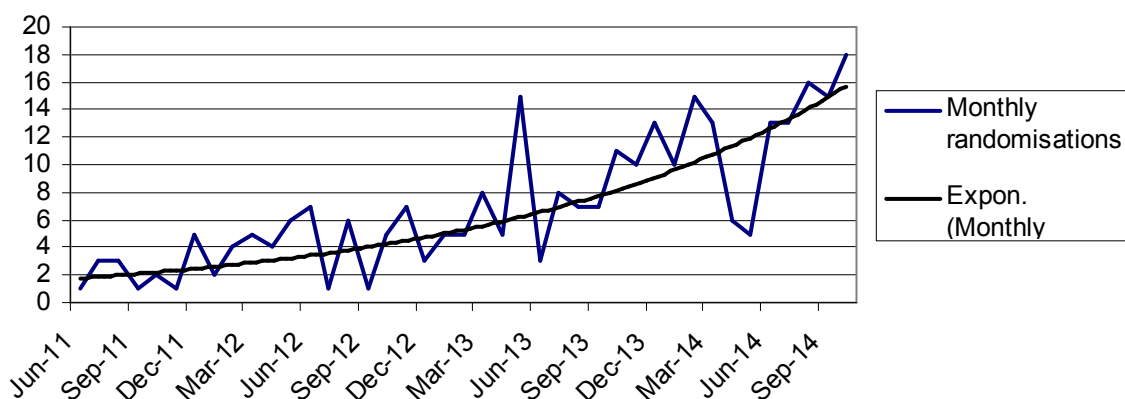
### Randomisations and Monthly Rate from Unit Opening—31.10.2014

### Randomisations from 1.04.2014—31.10.2014

Site	Total	Av rate
Birmingham Women's Hosp	10	1.11
St Mary's, Manchester	23	1.10
St Thomas's, London	43	1.05
Addenbrooke' s, Cambridge	34	0.83
Amsterdam Medical Centre	8	0.80
Leiden, Netherlands	4	0.67
Royal Bolton	18	0.67
Royal Victoria Infirmary, Newcastle	16	0.64
Arrowe Park Hosp, Wirral	5	0.63
Veldhoven, Netherlands	3	0.60
Norfolk & Norwich Uni Hosp	24	0.59
Medway Maritime Hosp	3	0.50
Imperial Healthcare Trust	16	0.47
John Radcliffe, Oxford	17	0.45
Isala, Netherlands	3	0.38
Sheffield Jessop	4	0.36
University Hospital Wales, Cardiff	8	0.32
Royal Oldham	3	0.30
James Cook, S Tees	6	0.30
Royal Gwent	7	0.29
St George's, London	3	0.27
N Ireland Network	5	0.20
New Cross, Wolverhampton	4	0.17
Royal Preston	4	0.16
Royal Cornwall, Truro	3	0.13
St Michael's, Bristol	1	0.11
Musgrove Park, Taunton	1	0.10
University Hospital N Tees	3	0.10
Bradford Royal	2	0.08
Sunderland Royal	1	0.05
Cork Maternity Hosp	1	0.05
Luton & Dunstable Hospital	1	0.03
Burnley General	0	0
Royal Berks Hosp, Reading	0	0.00
<b>Total</b>	<b>288</b>	

Site	No
St Thomas's, London	11
Amsterdam Medical Centre	9
Birmingham Women's Hosp	9
Arrowe Park Hosp, Wirral	5
St Mary's, Manchester	5
Addenbrooke's, Cambridge	4
Norfolk & Norwich Uni Hosp	4
Royal VI, Newcastle	4
Imperial Healthcare Trust	4
Isala, Netherlands	3
Veldhoven, Netherlands	3
James Cook, S Tees	3
Medway Maritime Hosp	3
Royal Bolton	3
Leiden, Netherlands	2
John Radcliffe, Oxford	2
Royal Gwent	2
Royal Oldham	2
Sheffield Jessop	2
Musgrove Park, Taunton	1
Royal Cornwall, Truro	1
Royal Preston	1
St Michael's, Bristol	1
University Hospital Wales	1
St George's, London	1
<b>Total</b>	<b>86</b>

**Monthly randomisations to PlaNeT-2 to 31.10.2014**



## The PlaNeT-2 Research Nurse Study Day

Over 40 people attended the PlaNeT-2 Research Nurse Study Day in London recently. It was wonderful to meet so many research nurses and clinicians who have a wealth of experience in research, and interest and enthusiasm for PlaNeT. Our aims for the day were to leave everyone better informed about the trial, learn from each other and to celebrate the trial success, and I believe we did achieve these objectives. I hope everyone who attended also found it a fun and enjoyable day—thanks to all for your active participation in the discussions.

We have put together 'Top 10 Tips' for PlaNeT-2 which has already gone out by email, but I have also reproduced it over the page for your information. The tips are really relevant to any trial that you are running.

If you would like any of the material from the day, please get in touch. I will also upload presentations on to the website



Karen, Anna & Julie celebrate a successful PlaNeT-2 study day

## The PlaNeT-2 Substantial Amendment

You will all hopefully be aware by now that we have Ethics Approval for a substantial amendment to the protocol. The new Protocol is V3.0. The reasons we felt we needed to amend the existing protocol are:

### 1 Collection of primary outcome data from babies transferred to other hospitals not participating in PlaNeT-2.

The protocol now stipulates clearly that we will seek to obtain data up to Study Day 28 if a baby is transferred to a non-participating unit (npu) before that time. Therefore when a baby on the trial is transferred to a npu, Form 7a and a copy of the consent form should go with the baby. We are requesting that the completed Form 7a is faxed back to the NHSBT by the receiving unit. The most important piece of data for the trial is the cranial USS performed at SD28 +/- 3 days. After SD28 we will not request this data from the new unit.



### 2 Permission to contact parents / GP / Health Visitor

We have added this to the protocol in order to help us obtain 2 year follow up data if the baby is not seen at the clinic where it was recruited to the study. As a result, we now have new informed consent forms (v2.0), Parent Info Sheet (v2.0) and ethically approved letters directed to parents and relevant health professionals for sending out around the 2 year stage.

### 3 National Database Data Extraction:

This has been added so we can extract data for trial purposes from Badger or a similar database. I know many of you have misgivings regarding the usefulness and accuracy of these databases, but it is hoped that in the future the completion rate and accuracy will improve.

### 4 End of Study for 'older' babies.

This was to clarify the confusion surrounding babies recruited to the trial after 34 weeks CGA. They **MUST be below 34 weeks CGA at BIRTH** to be eligible, but may be several weeks old when they are recruited. These babies will be above 38 weeks CGA at the primary outcome point, so we are asking you to collect 28 days worth of data

before they reach the End of Study (so for babies recruited at 36 weeks CGA, this will be 40 weeks CGA)

### 5 Change of end of trial date:

This has been extended to 31.12.2017 for the last randomisation date. We are optimistic that we will get to our target before that date though!

### 1 Research Ethos:

At induction of new staff and on introduction of parents to your unit emphasise that your unit is research active: 'Our unit is proud that we offer the opportunity to be part of important research projects...'. The National Institute of Healthcare Research (NIHR) aims to 'increase the opportunities for patients and the public to participate in, and benefit from, research'. **It is very important that parents are given the opportunity to participate** if they wish to do so. Studies show that the majority of parents will consent to multiple trials if given the opportunity.

### 2 Communication:

Improve communication between team members with a **specific research page** in the notes. Ideally make it coloured paper for quick identification. Record any discussions with parents regarding the trial, and approaches for informed consent. All entries should be signed and dated. Some units have found it helpful for this to form part of the handover. There is an example of a sheet for recording research discussions with parents on the website.

### 3 Training in PlaNeT-2:

Educate colleagues about the trial to improve awareness and embed the study in the unit. Consider dedicated induction sessions for research. Remind colleagues of the importance of the study by attendance at regular meetings, such as Senior Nurse Meetings. Some units produce monthly newsletters highlighting the research trials running in the dept

### 4 Marketing:

Use posters, laminated lanyards cards, PlaNeT-2 newsletters, mugs etc, to maintain the profile of PlaNeT. Contact Karen if you need any more.

### 5 Provide regular refresher training:

Best to make it fun. We have quizzes, presentations and games that can be sent out to reinforce PlaNeT-2 training.

### 6 Improving Consent Taking:

Consider running consent taking courses (run successfully by some Trusts).

### 7 Encourage GCP uptake:

This will help all your trials. Consider GCP Facilitator training.

For more information go to <http://www.crn.nihr.ac.uk/networks/>.

### 8 Be Competitive (optional!):

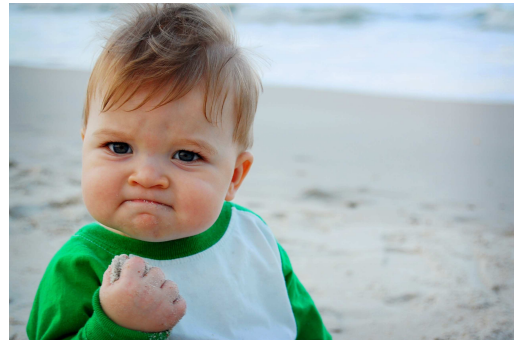
Some people like the competitive nature of recruitment and want to demonstrate how well they are doing to the unit. For those who like league tables, these can be produced monthly by Karen on request and circulated or posted up in the dept.

### 9 Be proud of your achievement:

This is an important study and every baby counts! If you are doing well, inform your R&D Dept and advertise your success. Recruitment to portfolio studies such as PlaNeT-2 brings additional income to the Trust for each randomised baby (in addition to the £300 randomisation fee). Extra recruitment should buy more research nurse time and will ultimately lead to better clinical care'

**Showcase your success!**

**Be proud of your success**



### 10 Share your knowledge and good ideas.

Let us know if you have developed a way of managing the trial more effectively and we can share it with everyone. We are considering using social media to heighten the profile of the study.