



## Spring 2015 Newsletter

### Editorial

Welcome to the latest edition of the Newsletter. It has been a very busy time for the trial since the last newsletter back in November. Since then we have randomised a further 62 babies to the trial, with 39 of those being randomised this year.

The milestone randomisations of babies No 300 & 330 have been achieved since the last newsletter. Baby No 300 was randomised by Sheffield Jessop, and No 330, which is the mid point of our target figure of 660, was achieved in February by Addenbrooke's. There is a short article about both teams in this newsletter. Since then the Royal Gwent have gone on to randomise Baby No 350, which we feel is another landmark moment for the trial.

We would also like to welcome a new site to the trial—William Harvey Hospital in Ashford, Kent. They have recently opened to recruitment.

It's really heartening to see some of the units that have been quiet have now started to randomise babies again. We appreciate that it is difficult to maintain interest in a trial that does not recruit quickly and research interests may change as staff come and go. As a result we have developed some tools that can be used to refresh knowledge regarding the trial; these include quizzes, presentations & posters. If you feel that there is anything that could be useful, please let the team here know. Don't forget that this is an important trial and your hard work will help to inform clinical decision-making based on good evidence.

*Best Wishes, Karen*

### News in Brief:

The number of babies randomised to Planet at 31.03.2015 is

**350**

Next TMG 22nd April

Next Research Nurse T/C: 29th April

TSC: TBC

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

### Meet the Teams

#### Sheffield Jessop —prize winners for Baby No 300

The Jessop neonatal unit is a 50 bed unit. It comprises of ITU, HDU and SCBU beds attached to the maternity services unit. Studies on the unit as well as the Planet-2 Trial, include feeding trials such as SIFT and Elfin. As well as other industry trials we also participate in academic studies for example looking at causes of SIDS and evaluation of family centred care.

We work in a team comprising of research nurses and midwives that cover areas from assisted conception, gynaecology and midwifery through to neonatal.

We also work collaboratively with the network research nurses for when infants are transferred to the other units in and around the area.

We were delighted to receive the Champagne for recruiting baby number 300. It arrived in time for our Christmas party, and we donated one bottle to the neonatal unit to be raffled off to the staff that worked Christmas day



Pauline Bayliss, Clinical Research Nurse, with Dr Porus Bustani, Consultant Neonatologist and PlaNeT-2 PI at Sheffield Jessop Hospital

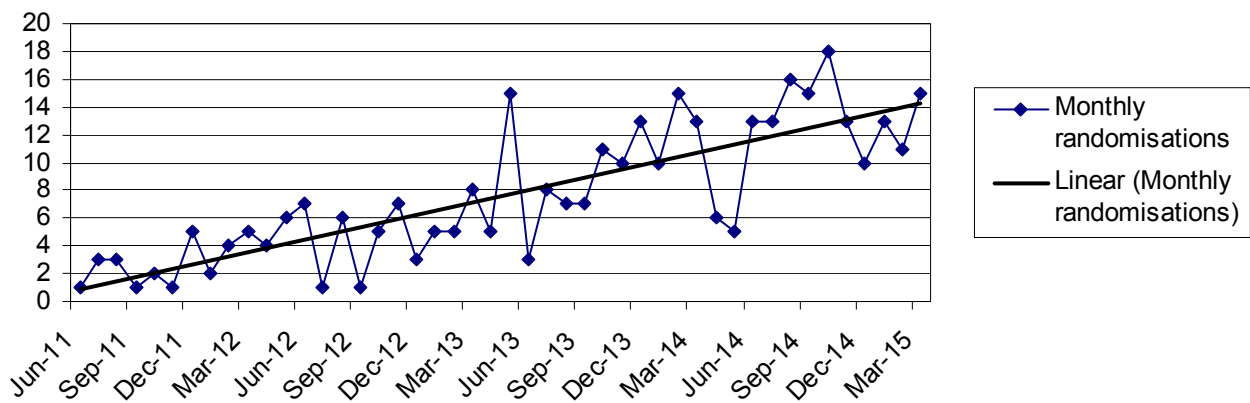
**Randomisations and Monthly Rate from Unit  
Opening—30.03.2015**

Site	Total	Average monthly accrual rate
St Thomas' London	48	1.02
St Mary's, Manchester	25	0.93
Amsterdam Medical Centre	13	0.81
Birmingham Women's Hosp	12	0.80
Addenbrooke's, Cambridge	36	0.77
Leiden Uni Med Centre	9	0.75
Erasmus Uni Med Centre, Rotterdam	5	0.71
Royal Victoria Infirmary, Newcastle	19	0.61
Sheffield Jessop Hosp	10	0.59
Royal Bolton	18	0.55
Maxima Med Centre, Veldhoven	6	0.55
Norfolk & Norwich Uni Hosp	25	0.53
Imperial Healthcare Trust	20	0.50
Uni Med Centre, Groningen	1	0.50
John Radcliffe Hosp, Oxford	21	0.48
Medway Maritime Hosp	5	0.42
Arrowe Park Hosp, Wirral	5	0.36
St George's, London	5	0.29
James Cook Hosp, South Tees	7	0.27
Royal Gwent	8	0.27
Uni Hosp of Wales, Cardiff	8	0.26
Royal Oldham	4	0.25
Isala Klinieken Zwolle	3	0.21
N Ireland Network	6	0.19
Burnley General	2	0.14
Uni Hosp North Tees	5	0.14
Royal Cornwall, Truro	4	0.14
New Cross, Wolverhampton	4	0.13
Royal Preston	4	0.13
St Michael's, Bristol	1	0.07
Bradford Royal	2	0.06
Musgrove Park, Taunton	1	0.06
Sunderland Royal	1	0.04
Cork Mat Hosp	1	0.04
Royal Berks Hosp, Reading	1	0.03
Luton & Dunstable Hosp	1	0.03
Portsmouth	4	n/a
<b>TOTAL</b>	<b>350</b>	

**Randomisations  
2015**

Site	No Randomised
Amsterdam Medical Centre	3
Erasmus Uni Med Centre, Rotterdam	3
Royal Victoria Infirmary, Newcastle	3
Sheffield Jessop Hosp	3
Maxima Med Centre, Veldhoven	3
Imperial Healthcare Trust	3
John Radcliffe Hosp, Oxford	3
St Thomas' London	2
Leiden Uni Med Centre	2
Medway Maritime Hosp	2
St George's, London	2
Uni Hosp North Tees	2
St Mary's, Manchester	1
Birmingham Women's Hosp	1
Addenbrooke's, Cambridge	1
Norfolk & Norwich Uni Hosp	1
Uni Med Centre, Groningen	1
Royal Gwent	1
Burnley General	1
Royal Cornwall, Truro	1

### Monthly randomisations to PlaNiT-2 to 31.03.2015



### Meet the Teams—Addenbrooke’s celebrate Baby No 330



**Heather Smethurst (Clinical Research Nurse), Me, Anna Curley (joint Chief Investigator), Angela D’Amore (Consultant Neonatologist and Trial Management Group member responsible for 2 year follow up) and Vidheya Venkatesh (Consultant and Cambridge PI)**

Here is the team from Addenbrooke’s in Cambridge that randomised baby No 330 and so qualified for the champagne and chocolates (some of you may have spotted that I have sneaked in to the photograph as well).

The NICU at Addenbrooke’s has 40 cots, of which 12 are designated ITU, 16 HDU & 12 SCBU beds. The unit is very research active with a number of trials, including studies covering neonatal neurology, haematology and respiratory medicine. The NICU at Addenbrooke’s also covers the Acute Neonatal Transfer Service (ANTS) which is the regional transport team for the East of England. Addenbrooke’s is part of East of England neonatal network which consists of 18 hospitals, and is one of three Level 3 units in the area (others are Norfolk & Norwich and Luton & Dunstable, both of which are also participating in PlaNiT-2)

Many of you will have met Anna Curley who has been working at Addenbrooke’s for the last 10 years or so, and is one of the driving forces behind the PlaNiT-2 trial. Since this photo was taken she has now moved to Dublin, but will remain very much involved in the trial and continues as joint Chief Investigator with Simon Stanworth who is based at Oxford. Anna is hoping that she will be able to bring Dublin into the trial later in the year.



Substantial Amendment

The next numbers to celebrate are 375 & 400. We are therefore offering a box of chocolates to the site that randomises Baby No 375, & champagne for No 400. The Royal Gwent Hospital randomised Baby No 350 and champagne will be on its way soon.

As well as the prize, the team that randomises the milestone baby receives PlaNeT admiration and an article with photograph in the newsletter!

**Be proud of your success**

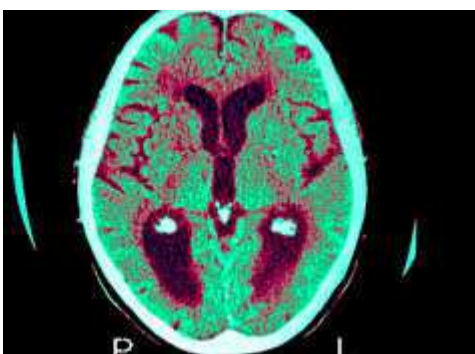


28 Day Scan

One of the most important pieces of data that we require for successful analysis of PlaNeT-2 at the end of the trial is the cranial Ultrasound Scan (CUSS) at Study Day (SD) 28. This will provide us with information for our primary outcomes. Recently we have been reviewing some of the CRFs and there are a few of these scans that seem to be missing for one reason or another, even if the baby is still within the recruiting unit. **Please could everyone try to ensure that a CUSS is performed at SD28 for randomised babies.**

There is a window of opportunity of +/- 3days to make this scan more obtainable. **However, if for whatever reason, you are unable to get a CUSS at this point, please attempt to scan at the earliest opportunity afterwards;** our medical experts will be able to review the results and possibly infer whether or not the baby suffered a bleed at SD28.

We are in the process of contacting sites in order to obtain more information if there is missing data. Thank you in advance for your cooperation!



I am aware that not all R&D Depts have given approval yet for the substantial amendment. So, in the next month or so I will be contacting sites to ascertain progress with the approval process for the amendment.

I am also intending to upload the new documents on to the website. Hopefully they should all be uploaded by the end of April.

Thanks to all for the help in pursuing approvals and providing localised documents for the new versions of the study materials.



Two year follow up

The team are looking at different ways of getting this information. One thing we would like to try is to design a card to be placed at the back of parent-held record cards. The card will serve 2 purposes—it will remind parents that they may be contacted at around 2 years' of age follow up information, but it will also give details of the website so that they can stay in touch with any new developments and follow results as they become available. Research has indicated that it is important to alert participants to the outcomes of a trial in which they have taken part. Those that are given this opportunity are more likely to agree to consent to trials in future.

We will need ethics approval for the card, but once we have this, we will send out to sites on request.