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hPOD Update: January 2016

Welcome to the hPOD newsletter! This is a monthly update for the hPOD research team and hospital staff so that we can all stay informed about how the trial is progressing. Any feedback or suggestions are always welcome.

Happy New Year- Welcome back!

We very much hope that you have had a bit of time off work, and that 2016 has started well for you all.

The hPOD Trial has now officially entered its second year! We are still...well...a few babies short of our goal of 2,129 babies, and we are looking forward to working with you all to maximise recruitment in all eight recruiting centres established last year.

In next month's newsletter, we will have the pleasure of introducing you to four new team members, including our new Lead hPOD Research Midwife, Siufofoga (Foga) Matagi who will replace our lovely Robyn Wilkinson. Also joining our Team in February are: Carla Saunders (Nurse, Auckland City Hospital), as well as Susan Law and Maree Young (Nurses, North Shore and Waitakere Hospitals).

A focus for the hPOD Study Team this year, will be strengthening relationships with hPOD Champions at each site, and the development of site-specific training. We will be making contact with each site to discuss clever, effective, ways we support you as you connect with and support others in the wider-site Team.

Our hPOD Study Teleconferences start back up in February, and are open forums to all. We would love you to join us.

Recruitment to the hPOD Main Trial this month (as at 28th January 2016)

Site/Hospital	Hawkes Bay	Waikato
Number randomised this month	3	8

TOTAL recruitment to date: 325

Thank you!

hPOD 2 year Follow-Up Study

An exciting milestone is reached this week with Dr Chris McKinlay travelling to Queenstown to complete our 100th two year old follow up assessment. Thank you to team members Dr Jo Hegarty, Dr Chris McKinlay, Dr Mariam Buksh, Dr Nataliia Burakevych, Dr Anna Tottman and Heather Stewart for their enthusiastic and valuable input to reach this number. The follow up study continues to be extremely well supported with families generously giving of their time especially on Saturdays.

We warmly welcome two new team members Dr Rebecca Griffith and Dr Alena Vasilenko who are currently learning the standardised developmental assessments required for the follow up. The numbers recruited on pre hPOD mean that we will soon need to assess 10 children per week to ensure all eligible children are seen. We have a further 21 children booked in already!



Welcome to Dr. Alena Vasilenko
hPOD 2 year Follow Up Study Team.

- Jenny Rogers, Clinical Research Coordinator, hPOD 2 year Follow Up Study.

Contacts for hPOD 2 year Follow up Study:

- Jenny (Study Coordinator): jenny.rogers@auckland.ac.nz
- hPOD 2 year Follow up Phone: 0800 249 537 or 021 980 913
- hPOD 2 year Follow up Email: hpod2followup@auckland.ac.nz

Gentle Reminders:

- **January Eligibility Forms and Trial Pack Audit Forms** - Please remember to send through your Monthly Eligibility Form, for *January*, and your Trial Pack Audit form to hpod@auckland.ac.nz or with your next courier pack.
- **hPOD Teleconference**
Next hPOD Teleconference: Friday 19th February 10:00am
Do you have time to join us!? Phone: 08 30 33, and enter Guest PIN: 461233.

Anyone is most welcome to join us - even if your site is not yet up-and-running. This is purely an opportunity to discuss how things are going, and share ideas. There is no 'monthly commitment', but we will be trying to change the day and time each month in an effort to offer those wishing to join us, the opportunity to do so.

hPOD Trial Quiz – January 2016

We would love you to try our (hopefully) fun quiz about the hPOD Trial. Feel free to print, share with- or forward this on to- as many colleagues as possible!

You're welcome to make use of the yellow hPOD Study Folders (each site has at least three) usually in the Birthing/Delivery Suite and in Post-Natal Wards to help you out with any particularly tricky questions.

The answers are at the end of the quiz. **The first 10 people to email hpod@auckland.ac.nz to tell us how you got on will be sent chocolate fish! (Please remember to include what site you are emailing from).**

So here we go... Good luck!

1. The study acronym 'hPOD' stands for:
 - a. Hypoglycaemia Placebo Or Dextrose.
 - b. Hypoglycaemia Prevention with Oral Dextrose.
 - c. Hypoglycaemia Prophylaxis with Oral Dextrose.
2. The primary outcome of the hPOD study (i.e. the key measurement of whether oral dextrose can successfully prevent neonatal hypoglycaemia) is:
 - a. Rates of admission to NICU/SCBU for > 4 hours.
 - b. Rates of hypoglycaemia.
 - c. Rates of formula feeding at 6-weeks of age.
3. Babies thought to be at-risk of hypoglycaemia, and who are therefore *potentially* eligible to take part in the hPOD study, are those who are likely to be born:
 - a. Small (< 10th percentile).
 - b. Large (>90th percentile).
 - c. Early (< 37 weeks gestation).
 - d. To a Mother with some form of diabetes (Type 1, Type 2, Gestational etc.)
 - e. All of the above
4. I am sitting with a Mum that I met at Clinic last week. Her baby is likely to meet the eligibility criteria for the hPOD Study and she has read through the Parent Information Sheet with her partner. They are really interested! The only thing is, she has just told me that she does not wish to breast-feed. Is that a problem for the Study?
 - a. No, that's not a problem.
 - b. ,Yes, that is a problem for the study. An intention to breastfeed is part of our eligibility criteria.
5. Where can one find information about the study?
 - a. The hPOD Study Parent Information Sheet (study brochure)
 - b. The hPOD Study website
 - c. The hPOD Study's Youtube video
 - d. Local site-staff and the hPOD Study Team.
 - e. All of the above.
6. A baby is born to a Mother who has consented to be part of the hPOD Study. What are the first two things that must be done before randomising the baby to the Study?
 - a. Sight the signed consent form and obtain verbal assent to participate from the parent/s.
 - b. Sight signed consent form, weigh the baby.
 - c. Obtain verbal assent from the family who you know agreed to take part in the study and weigh the baby.

7. When does randomisation to the hPOD Study need to occur?
 - a. Within the first 30 minutes after birth
 - b. Within the first hour after birth
 - c. Before birth
 - d. Randomisation can be done at any time after birth.

8. Why do I need to randomise the baby to a Trial Pack?
 - a. To reduce the risk of bias, ensuring that all babies are treated the same regardless of which Trial Gel they were given.
 - b. So babies are not 'picked' to be in one group or the other.
 - c. To ensure the numbers of babies in each group are large enough to potentially find a difference between groups.
 - d. All of the above.

9. Baby has not been allocated an NHI yet. What do I do?
 - a. Randomise baby using Mum's NHI.
 - b. Call the hPOD Study Team to get a 'dummy NHI' for the time being.
 - c. Baby cannot be randomised.

10. I don't have a hospital log-in and the hospital-based staff are busy. I want to randomise this consented, eligible baby. What can I do?
 - a. Nothing. You can only randomise using the computer.
 - b. Use your smartphone. Randomisation can occur using your iPhone or Smartphone.
 - c. Call the hPOD Study Team on 0800 004763 to help you with the randomisation.
 - d. Either b or c.

11. Will the randomisation website allow you to randomise a baby that does not meet the criteria?
 - a. Yes.
 - b. No, not if you have correctly entered the baby's details and they don't meet the study criteria.

12. Baby has been successfully randomised but I can't print out the form. What can I do?
 - a. Choose a Trial Pack from the fridge, noting on the CRF that the Randomisation Form could not be viewed and that a Trial Pack was selected at random.
 - b. View the Randomisation Form from the screen. The Form is saved to the Baby's record on the website and can be printed at a later time at the site, or at Liggins.
 - c. Nothing. I can't move forward with the Study process.

13. hPOD Trial Packs contain:
 - a. Dextrose only.
 - b. Dextrose OR Placebo.
 - c. Placebo only.

14. Can hPOD Trial Packs be used as Treatment Gel?
 - a. Yes, because both the Trial Packs and Treatment Gel contain 40% Dextrose.
 - b. No, because this is a Protocol Violation and will stop the Trial.
 - c. No, because half of the hPOD Trial Packs contain placebo gel so the baby would not get the treatment he/she requires.

15. Can baby breastfeed before and/or after the hPOD Trial gel is given?
 - a. Yes, baby can breastfeed before the Trial Gel is given, but not after.
 - b. Yes, baby can breastfeed after the Trial Gel is given, but not before.
 - c. Yes, baby can breastfeed before and after the Trial Gel is given.

16. A baby in the hPOD Study has a low blood glucose measurement and according to your local treatment protocol requires treatment with dextrose gel. Do you:
 - a. Collect another hPOD Trial Pack from the fridge to administer, as this is an hPOD-baby.
 - b. Locate your local dextrose gel container or syringes used for babies not in the trial and administer this gel.
 - c. Don't give treatment dextrose gel, because the baby has already had a dose of trial gel.

17. Why does the hPOD Study ask that all blood glucose readings be taken using an approved glucose-oxidase method (iSTAT, EPOC, Lab, Blood Gas)?
 - a. These methods are accurate at low blood glucose concentrations. Bedside strip tests are not.
 - b. Using accurate glucose oxidase methods means that you avoid having to take a second reading if the first reading is low.
 - c. To be difficult.
 - d. Both a and b.

18. Baby has had the Trial Pack gel, and all the bloods. What happens now?
 - a. Nothing, all data has been collected.
 - b. The family are asked at Discharge and contacted on Day 3 to ask primarily what method of feeding (breast vs formula, or both) they are using.
 - c. The family asked at Discharge and contacted on Day 3 regarding feeding method (breast vs formula, or both) and then again at 6 weeks regarding feeding and their experience of the Study.
 - d. The family are asked at Discharge and contacted on Day 3 regarding feeding method (breast vs formula, or both) and then again at 6 weeks regarding feeding, their experience of the Trial and whether they are interested in being contacted for follow-up when their baby is 2 years old. A First Birthday Card is also sent when baby turns 1.

How did you go? Some were easier than others! Please let us know if there was a question or two that was particularly tricky or further questions provoked from those in the quiz. It gives us a great idea of what to revise or provide further information about.

The role of the hPOD Study Team is to support you to feel confident in your knowledge and implementation of the Trial. Please feel free to make use of us! Suggestions are always welcome.

Contacts:

- Kelly Fredell (Study Coordinator): k.fredell@auckland.ac.nz or on (09) 923 7720.
- Siufofoga (Foga) Matagi (Lead hPOD Research Midwife) for clinical support (from February 2016 onwards, contact details to come).
- hPOD Study Phone: 0800 004 763.
- hPOD Study Email: hpod@auckland.ac.nz

Resources:

- The hPOD study page on the Liggins Institute website <http://www.liggins.auckland.ac.nz/hpod>
- The hPOD randomisation website here <https://www.ligginstrials.org/hPOD>
- On YouTube <https://www.youtube.com/watch?v=Jh4XUHgBFdU>



Answers to the Quiz:

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|-----|------|------|
| 1 b | 7 b | 13 b |
| 2 a | 8 d | 14 c |
| 3 e | 9 a | 15 c |
| 4 b | 10 d | 16 b |
| 5 e | 11 b | 17 d |
| 6 a | 12 b | 18 d |