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AUSTRALASIAN
**KIDNEY
TRIALS
NETWORK**

AUSTRALASIAN KIDNEY TRIALS NETWORK

HONEYPOT Newsletter

Seasons Greeting from the HONEYPOT Study

The HONEYPOT Trial is proceeding very well, with most sites successfully recruiting patients, and 58% of the total recruitment target already achieved.

On behalf of the HONEYPOT Trial Management Committee, I would like to thank all site Investigators and Coordination staff for their hard work and dedication this year. We are looking forward to another productive year in 2010, which hopefully will see the HONEYPOT recruitment target met!

Since I have now commenced in a Project Manager role at the AKTN, the HONEYPOT trial will now be centrally coordinated by AKTN Project Officer Liza Vergara (see details below). I will still be actively involved in the HONEYPOT and all AKTN trials, so look forward to our continued collaborations in the New Year.

I wish everybody a wonderful and safe festive season. *Bee* seeing you!

Cheers,

Alicia Smith
AKTN Project Manager

New Project Officer!

I will be the Project Officer for HONEYPOT starting 2010! Some of you may already know me, aside from the HONEYPOT trial, I'm also coordinating the BLOCADE trial. Have a nice festive season and I will see you in the New Year!



Cheers,

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The
HONEYPOT
AKTN 06.02
trial

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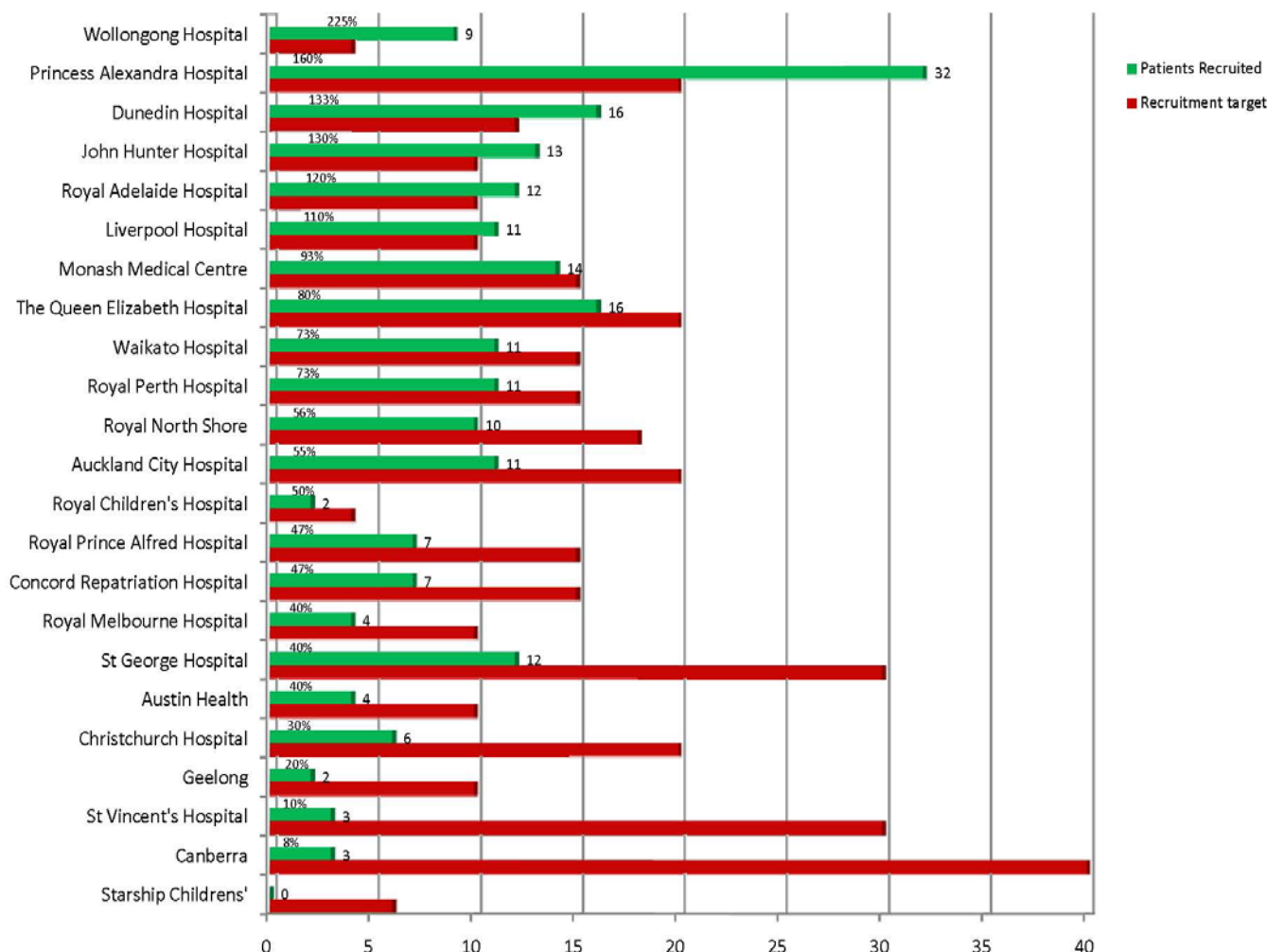
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Recruitment Update

23 sites are now actively recruiting. The total number of patients recruited is 216, which is 58% of the total recruitment target.

Princess Alexandra Hospital have enrolled the most patients to date (32 patients), followed by Dunedin Hospital and The Queen Elizabeth Hospital with 16 patients each.

Recruitment is proceeding especially well at the following sites, who we congratulate for already meeting or exceeding their original recruitment target: Wollongong Hospital, Princess Alexandra Hospital, Dunedin Hospital, Royal Adelaide Hospital and Liverpool Hospital.



Recruitment Reminder

Although recruitment is proceeding pretty well on target, we cannot afford to let down our guards! As patient follow-up must continue for 12 months after patient #370 is randomised to the trial, if we take longer to achieve this target of 370, then the length of follow-up for all existing patients increases as well. If you are struggling to achieve your recruitment targets,

DON'T FORGET TO SCREEN INCIDENT PD PATIENTS !

(those new to PD, ie commenced PD within previous 12 weeks)

New Sites

We have 2 new sites, Royal Hobart (PI Dr Geoffrey Kirkland and Research Nurse Gail Read) and Mater Children's Hospital (PI Steven Dr Steven McTaggart and Study Coordinator Simone Taylor) who are currently completing their documentation to be able to start recruiting. We anticipate recruitment to start early next year.

Monitoring Updates

A total of 14 sites have now had at least one monitoring visit; Auckland City Hospital, Christchurch Hospital, Concord Repatriation Hospital, Dunedin Hospital, John Hunter Hospital, Monash Medical Centre, Princess Alexandra Hospital, Royal Adelaide Hospital, Royal Children's Hospital, Royal Melbourne Hospital, Royal Perth Hospital, Royal Prince Alfred Hospital, The Queen Elizabeth Hospital and Waikato Hospital have all been visited. From these visits, the following have come to light as important issues to consider whilst recording data for the trial.

The importance of Source Documentation

Source documentation should be available for every piece of data that is entered into the CRF. The cardinal rule for Clinical Trials data is: **If there is no source from which to verify it, there is no data!** Also the source is the FIRST place the information was recorded. Therefore it is acceptable to use the provided visit stickers for weight, BP etc as it is feasible that this is the first place you would record this after taking the measurements. However for data found on the Baseline PD eCRF, the PD adequacy reports and similar, the source that you accessed this data **MUST BE AVAILABLE** for data verification (eg reports or pages from online databases printed and copies placed in the source document folder) The most frequently encountered issues at monitoring include:

- Tenckhoff catheter specifications at Baseline (missing data) - this data is often missing or cannot be verified from any available source document. If this information is known to the treating physician but not able to be verified from source (eg surgical notes) due to this information not being recorded for every patient, this should be recorded as a file note in the patient's source document folder (eg "*catheter inserted was the standard used at Royal Honey Hospital: straight, 1 cuff, no swan neck. Information not routinely recorded in surgical notes*").
- Deviation log entries for visits out of schedule - whenever a bi-monthly study visit occurs outside the scheduled visit (and a query is fired in the InForm eCRF), this should be recorded on the Protocol Deviation log and faxed to the AKTN.
- File notes - whenever a protocol deviation, or any thing else *unusual* occurs in the trial (eg patient initials recorded incorrectly at randomisation) a file note should be completed and filed in the source document folder. These are inspected during any monitoring visit by a monitor or by an auditor.
- Nasal swab CRF at baseline for control patients - often this CRF is empty because this is missed as the tab (NSwab) is "hiding" under the Visit tab. You will know that this CRF is missed by the yellow traffic lights shown on the Baseline CRF page. Please check that the Baseline CRF is complete.



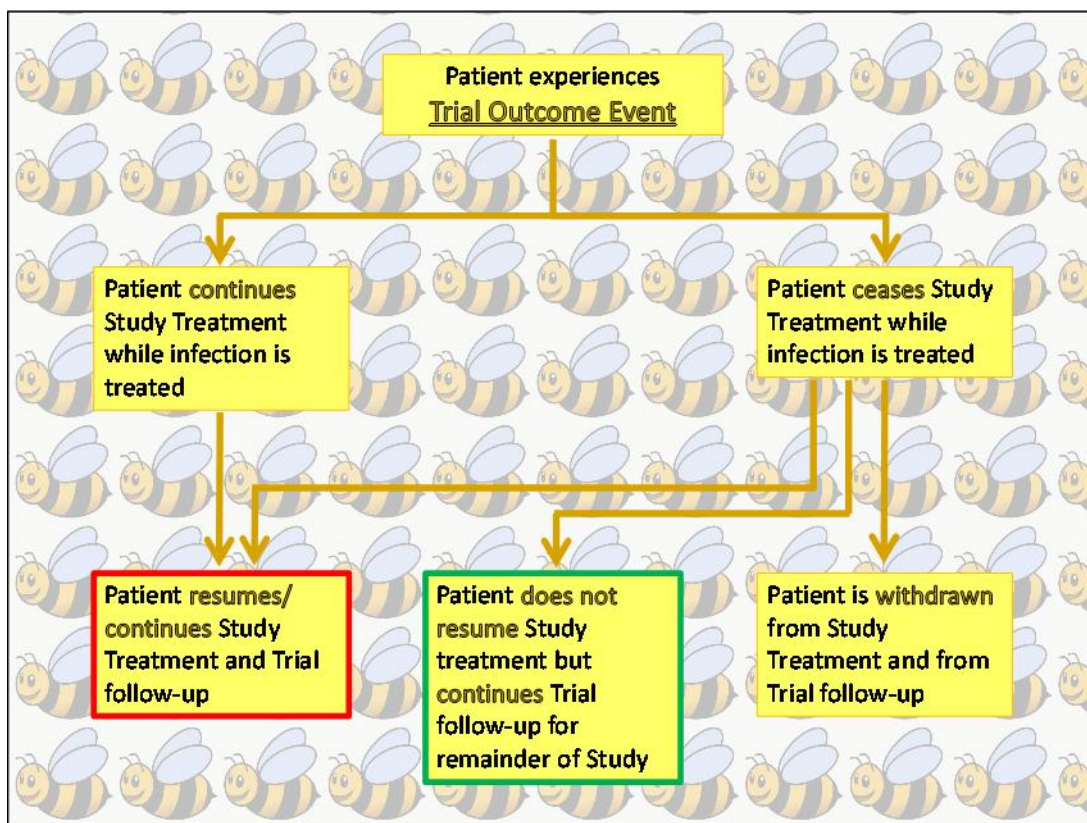
Changes to the Study Protocol

The Safety and Data Monitoring Committee (SDMC) for the HONEYPOT study met in October 2009 and discussed various aspects of the study. The SDMC concluded that there was no safety concerns and the trial should continue recruiting. A second interim analysis will be done when 2/3 recruitment is reached.

The SDMC suggested only minor recommendations. Protocol amendments will be submitted to UQ Ethics in January 2010 and subsequently will be sent to sites.

End of Study – when to withdraw, when to continue follow up?

We have had several queries about what to do if a patient reaches a Trial Outcome Event. The following flowchart should help clarify the choices available. The preferred option is highlighted in **Red**, with our second preference in **Green**, but clinical decisions are left to the discretion of the treating physician.



Latest interest s in HONEYPOT

Jassal SV, Lok CE. Honey-pot: Sticky or sweet? *Per Dial Int.* 2009; May-Jun; 29(3):303-309.

Johnson DW, Clark C, Isbel NM, Hawley CM, Beller E, Cass A, de Zoysa J, McTaggart S, Playford G, Rosser B, Thompson C, Snelling P; HONEYPOT Study Group. The HONEYPOT study protocol: a randomized controlled trial of exit-site application of medihoney antibacterial wound gel for the prevention of catheter-associated infections in peritoneal dialysis patients *Perit Dial Int.* 2009 May-Jun;29(3):303-9.

Piraino B. Mupirocin for preventing exit-site infection and peritonitis in patients undergoing peritoneal dialysis. Was it effective? *Nephrol Dial Transplant.* 2009 Nov 24.



FAQs

For Further Information :

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Q: Are patients enrolled in other trials eligible for inclusion in HONEYPOT?

A: Absolutely! As long as the patients meet all inclusion criteria and no exclusion criteria, there is no reason they can't be involved in other clinical trials at the same time as HONEYPOT. It is a good idea to check with the Study Coordinator or Sponsor of any other trials your patients may be involved in though, to ensure they do not have any restrictions of this kind.

Q: In what time frame must the Baseline visit occur with regards to Randomisation?

A: The Baseline visit must be within 14 days of Randomisation (after Randomisation). This is to ensure the currency of the nasal swab that is conducted at Randomisation. At some sites however, it may be more convenient for the Baseline visit (or at least some of the Baseline assessments) to occur *prior* to Randomisation. This is also acceptable, just be sure to record the dates accurately. If Baseline is conducted prior to Randomisation, the information will need to be recorded on visit stickers or paper based CRF template first, as the electronic CRF is not made available in InForm until after Randomisation.

Q: Are patients randomised to the control arm who are not nasal carriers of *S. aureus* required to maintain a Medication Diary?

A: No, if a Control arm patient is not a nasal carrier of *S. aureus*, then no medication is required, and as a result no Medication Diary is required. The trial Medication Diaries have been provided as non-compulsory trial resources and are therefore not considered source documents. A site or patient may choose not to maintain one, as long as they can reliably relay their study medication compliance at their bimonthly study visits.

HONEY funnies

Q: Who is the bees' favourite singer?

A: Sting!

Q: Who is the bees' favourite pop group?

A: The bee gees!

Q: Who is the bees' favourite classical composer?

A: Bee-thoven!

Q: What does a queen bee do when she burps?

A: Issues a royal pardon!

