



Dear All

Welcome to the second newsletter of the Favoured Study. There has been significant progress with the study made since the first newsletter. We now have three randomised patients. Congratulations to Dr Eugenie Pedagogos and Tia Raspudic at the Royal Melbourne Hospital for randomising Patient Number One. We have 7 sites that are currently recruiting including Royal Perth Hospital, Princess Alexandra Hospital, Launceston Hospital, Toowoomba Hospital, Queen Elizabeth Hospital and The Austin.

Between the end of May and the beginning of June, the AKTN held three meetings in Melbourne, Sydney and Auckland for our study coordinators and investigators. We had a total of 33 site staff participate from a total of 23 sites. These meetings gave us the opportunity to refresh the study procedures in the minds of ongoing site staff and to meet and initiate new staff.

The meetings were also an opportunity to clarify with site staff important aspects of the study protocol. Queries from site staff covered a broad range of topics such as recruitment & screening, medication, funding, timing

of visits, CRFs & documentation, staffing, AEs/SAEs and pathology. Questions of particular interest have been included in this newsletter with the complete list of questions and answers available from me.

We are currently putting together the finishing touches on the format of the web based system for randomising patients (the Flexetrials system). The final version will be available soon, along with a training and users manual. The complete electronic CRF is also currently in production and should be available by the end of the year.

Cheers

Peta-Anne Paul-Brent
AKTN Favoured Central Coordinator



■ Site Status

Interested Sites	29
Sites undertaking Ethics	9
Sites with Ethics Approval	20
CTA signed	7
CTN completed	10
Sites Actively Recruiting	7
Participants Screened	25
Participants Randomised	3

■ Study Coordinators Meetings

As the Gold Coast study initiation meeting for Favoured was held over 6 months ago, it was decided to hold Study Coordinator meetings for all current sites to update staff on any new developments, and provide new research staff with the information required to conduct the trial at their site. Three meetings were held in Melbourne, Sydney and Auckland and we have a total of 33 study coordinators and investigators from 23 sites.

19 th May 2008	26 th May 2008	9 th June 2008
Melbourne Airport Hilton Hotel	Stamford Plaza Sydney Airport Hotel	Jet Park Airport Hotel, Auckland
<i>Site attended</i>	<i>Site attended</i>	<i>Site attended</i>
Austin Health Monash Medical Centre Geelong Hospital Royal Adelaide Hospital St Vincent's Hospital Launceston General Hospital The Alfred Hospital Queen Elizabeth Hospital Royal Melbourne Hospital Flinders Medical Centre	The Canberra Hospital Townsville Hospital St George Hospital Liverpool Hospital Royal North Shore Hospital Prince of Wales Hospital Gold Coast General Hospital Royal Prince Alfred Hospital Wollongong Hospital Nambour General Hospital Toowoomba Base Hospital	Middlemore Hospital Auckland Health District

The meetings also gave sites a chance to discuss any issues they had with AKTN staff. Many questions were raised, and a list of these and their resolutions were distributed to all current sites. A sample of the issues discussed can be found below. For a copy of the full document, or to discuss any of these issues, please feel free to contact Peta on p.kerr@uq.edu.au

Q/A from the Study Coordinators Meetings

1. What level of screening needs to be entered into the screening log? Anyone who was superficially considered? Anyone who was approached?

2. If patient has been approached/considered for the trial but not consented due to ineligibility, can this be recorded in the screening failures log without the consent of the patient?

3. What happens if patient doesn't take the medication on the day prior to the surgery (dose 1)? Should these patients be excluded?

4. The 7 day period between Baseline and Randomisation is too restrictive for country patients attending large centres, where the patient is often seen 2 weeks or more prior to surgery, then not again until day of surgery.

5. What are the time windows for each of the scheduled visits?

1. Best practice is to record all patients who were superficially suitable then specify why not they were or were not eligible. This will assist with justifying patient recruitment rates etc.

2. Identified patient information is OK to be collected by research unit, as long as screening log that is sent to AKTN is de-identified. An electronic screening spreadsheet has been developed that allows sites to enter indentifying information which can removed to send to AKTN.

3. No, don't exclude. If patients have forgotten the pre surgery dose of study medication, the patient can take the medication the morning of the procedure. If this is not possible, just note on CRF. This medication compliance issue should be noted separately on the CRF to the usual medication compliance question.

4. After a meeting of the study's TMC, it was decided that the time between baseline and surgery would be increased to four weeks. Randomisation should be maintained at up to 7 days but it does not need to occur in the patient's presence. Randomisation can be done over the phone then medication pack can be posted to patient so the first dose can be taken on the day prior to surgery.

Week 1	1 day before/ 1 day after
Week 6	7 days before / 7 days after
Week 12	7 days before / 7 days after (blood must be taken while still taking study medication and there will be a maximum 13 week supply)
Month 6	14 days before / 14 days after
Months 12 - 36	28 days before / 28 days after

Q/A from the Study Coordinators Meetings

6. For country sites/patients, can the labs (eg bloods) be done at a local laboratory? This will be especially relevant for tests requiring patient fasting.

6. Yes, country patients can have their blood samples collected and processed at their local hospital. The AKTN will need the NATA certification from all laboratories processing samples and it will be the responsibility of the study coordinator at the main site to consider collection and storage of the batched samples.

7. Are specific types of tubes required for the samples? Can AKTN supply cryostable tubes?

7. The batched samples (7 per patient) are collected using standard serum, EDTA and urine collection tubes and can usually be obtained from the site pathology laboratory. The AKTN will be providing the cryostable storage tubes, labels for tubes and bags to store tubes.

8. Are ALL AEs to be collected, or just those related to the study medication?

8. After a meeting of the study TMC, it was decided that only AEs that the site investigator rates as possibly, probably or definitely related with the study medication will be recorded. These will primarily include bleeding events (relating to aspirin) and gastrointestinal symptoms (relating to the fish oil). All SAEs will still need recorded, whether related to the study medication or not.

9. Are specific types of tubes required for the samples? Can AKTN supply cryostable tubes?

9. The batched samples (7 per patient) are collected using standard serum, EDTA and urine collection tubes and can usually be obtained from the site pathology laboratory. The AKTN will be providing the cryostable storage tubes, labels for tubes and bags to store tubes.



AUSTRALASIAN
**KIDNEY
TRIALS
NETWORK**

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