

NEWSLETTER

Vol. 3, February 2009

Dear All

The start of 2009 sees a number of important steps forward in the progress of the Favoured Study

- We now have 14 sites actively recruiting patients with another 19 sites at various stages of gaining ethical and governance approval. The new active sites include the Gold Coast Hospital in Queensland, the Royal Adelaide Hospital in South Australia, Monash Medical Centre in Victoria, Fremantle and Sir Charles Gairdner Hospitals in Western Australia, and the Prince of Wales, Royal Prince Alfred and Royal North Shore Hospitals in New South Wales. Even with the inevitable slow down of access surgeries over the Christmas/New Year period, we now have 19 participants enrolled in the study.
- The Favoured Trial Management Committee is currently looking at the possibility of expanding the potential for rapid recruitment by including new sites in China, Malaysia and the United Kingdom. Initial enquires and establishment of local contacts is encouraging and we should have more information for inclusion in next issue of the Favoured Newsletter
- There have been some changes to the membership of the Favoured Trial Management Committee. We would like to welcome back Dr Sharan Dogra of Sir Charles Gairdner Hospital, who has returned from maternity leave to rejoin the Committee. We would also like to welcome Dr Vlado Perkovic from the George Institute and Dr David Voss from Middlemore Hospital to the TMC. Dr Voss is taking the place Dr Johan Rosman who has been invaluable over the last two years with his participation the Favoured Study protocol development and insight

into the New Zealand prospective. Welcome to our new and returning members and many thanks to Dr Rosman.

- The last few months of 2008 saw some important changes with the study. There was the release of the latest version of the study protocol – Version 8, and the introduction of the web based system for randomising patients, Flexetrial as well as the electronic case report form (web based InForm system).
- Another important milestone reached at the end of last year was the acceptance by BMC Nephrology of the article describing the study design and methodology called “Preventing AVF thrombosis: the rationale and design of the Omega-3 fatty acids (Fish Oils) and Aspirin in Vascular access OUTcomes in REnal Disease (FAVOURED) study.” You will be able to view the article by following this link: <http://www.biomed-central.com/1471-2369/10/1>

2009 looks like it will be another important and busy year for the Favoured Study.

Yours Sincerely

Ashley Irish & Peta-Anne Paul-Brent

Favoured TMC Chairman & AKTN Favoured Central Coordinator



• Site Status

The new active sites include the Gold Coast Hospital in Queensland, the Royal Adelaide Hospital in South Australia, Monash Medical Centre in Victoria, Fremantle and Sir Charles Gairdner Hospitals in Western Australia, The Canberra Hospital in the ACT, and the St George, Liverpool, Concorde General and Repatriation, Prince of Wales, Royal Prince Alfred and Royal North Shore Hospitals in New South Wales.

Interested Sites	33
Sites Undertaking Ethics	10
Sites With Ethics Approval	23
CTAs Signed	20
CTN Completed	19
Sites Actively Recruiting	18
Participants Enrolled	22

• Version 8 of the Study Protocol

In December of last year, a new version of the study protocol, Version 8, was introduced.

Key changes to the protocol were instituted following the conclusion and reporting of the Clopidogrel study in the United States. The results of this study emphasised the importance of not just the primary patency of AVFs but also the suitability of the AVF as a haemodialysis access (its functional patency). To this end, an additional outcome measure was included to the protocol – functional patency measured at 12 months – to allow patients who do not start dialysis within 6 months of access surgery to be included in the analysis of the functional patency. Also included was an sample calculation for the functional patency to ensure that the study had sufficient power to reach a significant result for this key outcome.

Other changes to the protocol include:

- Updated details of the members of Trial Management Committee
- More detailed information about study outcomes and what constitutes an end of study event
- The requirement to only report adverse events that are possibly or probably related to the study medication. This requirement does not include Serious Adverse Events, with all SAEs, related or not, still needing to be reported.
- The possible involvement of new sites in overseas countries including China, Malaysia and the United Kingdom.

• Introduction of the Flexetrials and InForm Systems

The online randomisation system using the University of Sydney Clinical Trials Centre's program 'Flexetrials', has been available to sites since October. Study coordinators at 11 sites have now completed the training for the system and are able to randomise patients using the Live Version of Flexetrials.

The online electronic case report forms (eCRF), using the 'InForm' software system, developed by a Sydney-based company Phase Forward, was made available to sites for training in December 2008. The training for the system has now been completed by 1 site. The InForm system will have a number of useful features including an electronic copy of the Operation Manual available online and a list of the Frequently Asked Questions that can be updated regularly.

With the introduction of the InForm system, a new version of the Operations Manual has been produced. Version 3 of the Operations Manual incorporates the new guidelines relating to the use of the InForm system (including a detailed outline of the data collected by each of the forms) and the key changes made to the study design with the introduction of Version 8 of the study protocol. A new version of the paper CRF has also been created to act as a companion to the electronic CRF. It directly reflects the content of the eCRF and is designed to act as source documents if the electronic system is unavailable.

Q/A from the Study Coordinators Meetings

1. Can patients that are enrolled in other studies such as the Sharp Study, be enrolled in the Favoured Study?

2. Is it necessary to count the study medication at each of the treatment visits?

1. As long as the other study does not exclude participation in other studies and the medication/treatment used in the other study will not interact the Favoured Study medications, patient are able to participate in multiple studies concurrently. It is important that site staff check with their site's HREC to ensure that the individual ethics committees have no specific guidelines about patients participating in more than one clinical trial.

2. Yes. At each treatment visit (week 1, 6 and 12) the patient's study medication should be collected by study staff and counted. It is, however, important to remind patients that they should finish the first bottle of the fish oil capsules before opening the second bottle. The table below gives the approximate number of capsules and tablets that should remain at each treatment visit if the patient attends their visit on the correct day and have been taking their medication correctly. Patients should not need to start the second bottle of fish oil until after the week 6 visit.

	Week 1	Week 6	Week 12
Fish Oil Capsules	332	192	24
Aspirin Tablets	83	48	6

3. How do I collect a patient's data for their Screening and Baseline visits if the InForm system only "creates" a patient when the patient is randomised using the Flexetrial system?

3. The data to be collected for patients at the Screening and Baseline visits must be first collected using paper forms (RS and BM) and then entered in InForm once the patient has been randomised. The forms RS (Randomisation and Screening) and BM (Baseline and Medication) have been designed as companions to the inform system forms (they directly reflect the contents of the online forms) and after entry into the InForm system, should stored as source documents.

Q/A from the Study Coordinators Meetings

4. Are all patients who are taking aspirin unsuitable for the study?

4. Although many patients take aspirin, not all actually have a medical indication to take it ie they may be self medicated or have been prescribed aspirin “Just in case”. It is important, when screening patients for their suitability for the study that study coordinators assess (by asking patient and/or treating physician) whether the patient would be able to cease aspirin for the duration of the study treatment period.

A couple go on vacation to a fishing resort. The husband likes to fish at the crack of dawn. The wife likes to read. One morning the husband returns after several hours of fishing and decides to take a nap. Although not familiar with the lake, the wife decides to take the boat out. She motors out a short distance, anchors, and continues to read her book.

Along comes a forest policeman in his boat. He pulls up alongside the woman and says, “Good morning Ma’am. What are you doing?”

“Reading a book,” she replies, (thinking “isn’t that obvious?”)

“You’re in a restricted fishing area,” he informs her.

“I’m sorry officer, but I’m not fishing, I’m reading.”

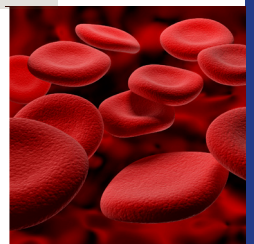
“Yes, but you have all the equipment. I’ll have to take you in and write you up.”

“If you do that, I’ll have to charge you with sexual assault,” says the woman.

“But I haven’t even touched you,” says the policeman.

“That’s true, but you have all the equipment.”

MORAL: Never argue with a woman who reads. It’s likely she can also think!



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