



AUSTRALASIAN
**KIDNEY
TRIALS
NETWORK**

Seasons Greeting from the FAVOURED Study

As we reach the end of 2009, we can look back and see what a busy year it has been.

The Trial Management Committee and myself would like to thank all the study staff at sites for their hard work and dedication this year and we are looking forward to 2010 with 95% of the Australian and New Zealand sites actively recruiting and with the inclusion of the new overseas sites.

I hope that everybody has a Wonderful Festive Season and see you in the New Year.

Cheers

FAVOURED Project Officer

Peta-Anne Paul-Brent



New Overseas Sites

The FAVOURED Study is being extended into new overseas sites. We will be first introducing sites in Malaysia and the United Kingdom with the aim of starting these sites in the New Year. Once these sites are up and running, we will review the possibility of including sites in Canada and China.

United Kingdom

We are working with Drs Colin Hutchison and Chris McIntyre (from Queen Elizabeth Hospital, Birmingham and Derby City Hospital respectively) and 4 - 5 sites interested in participating with a minimum recruitment target of 100 patients per year. We are aiming to start recruiting patients in the first quarter of 2010.



Malaysia

In Malaysia, we are working with Dr Hooi Lai Seong as lead Principal Investigator from Hospital Sultanah Aminah in Johor and we have 9 interested sites with a minimum recruitment target of 100 patients per year. We are aiming to start recruiting patients early in the New Year.



Inside this issue:

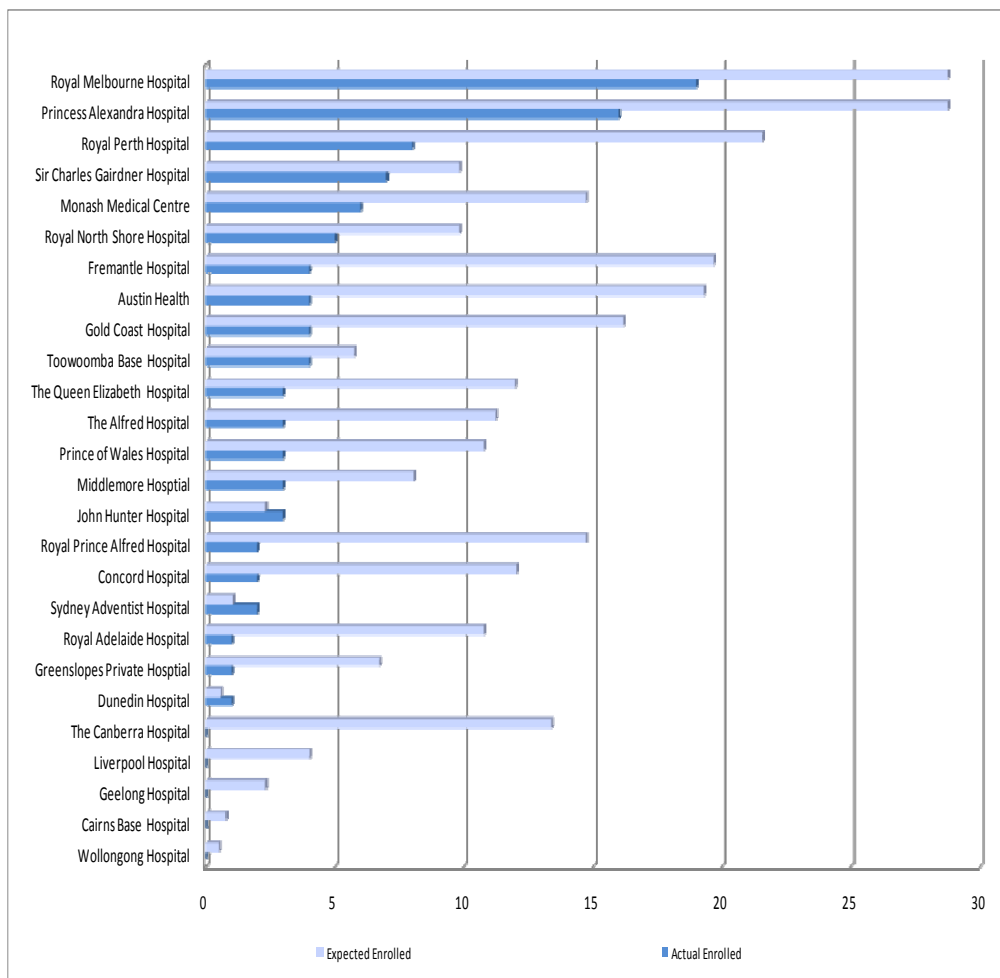
ANZ Site Status	2	Questions from Sites	4
Regional Champions	2	Monitoring	4
Aspirin Usage	3	Fishy Humour	4
Changes to Protocol	3		

Australian and New Zealand Site Status

We now have 26 sites actively recruiting; 21 of those which have enrolled at least one patient. The total number of patients is 101.

Royal Melbourne and Princess Alexandra Hospitals have the highest number of patients enrolled, 19 and 16 patients respectively.

Dunedin, Sydney Adventist, and John Hunter Hospitals have the best percentage of what they expected with all 3 sites at over 100% recruitment.



Regional Champions

The Trial Management Committee has appointed a Champion from each participating Australian state and overseas country involved in the FAVOURED Study. The Champions will be in regular contact with each of the sites in their region and will act as the resident cheerleader, advocate and/or slavedriver (depending on what is needed). All champions are also now members of the TMC and will be able to discuss any new TMC developments with the sites.

The **Australian Regional Champions** are:

Queensland.....Carmel Hawley

New South Wales.....David Gracey

New South Wales.....Amanda Mather

Victoria.....Kevan Polkinghorne

South Australia.....Chen Peh

Western Australia.....Ashley Irish

The **Regional Champions for the Overseas Countries** are:

New Zealand.....David Voss

Malaysia.....Hooi Lai Seong

United Kingdom.....Colin Hutchison

United Kingdom.....Chris McIntyre



Aspirin Usage

An analysis of site screening logs shows that so far 1140 patients have been screened, with the most common cause of screening failure current use of aspirin accounting for 27.2% of all screened.

“it would be safe to stop aspirin unless there is an absolute indication for aspirin (eg. documented ischaemic heart disease)”

The value of aspirin in ESKD remains uncertain. It is not clear whether aspirin improves vascular access patency, as some studies showing favour-

able and other showing harmful results.

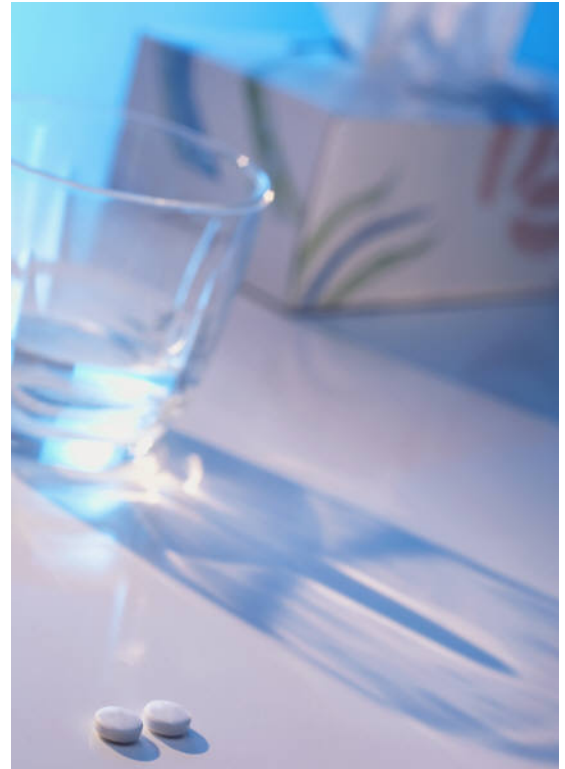
A recent meta-analysis of aspirin in 6 primary prevention trials in the general population concluded that aspirin was of uncertain value in primary prevention. A recent sub-analysis of the HOT study suggested aspirin was likely to be beneficial in patients with early CKD (Stage 3), but also showed an increased risk of bleeding in these individuals.

Hence, based on the currently available evidence, the FAVOURED TMC is of opinion that it would be safe to stop aspirin unless there is an absolute indication for aspirin (eg. documented ischaemic heart disease).

Our view is supported by the findings of the recently published DAC trial of dipyridamole plus aspirin on haemodialysis graft patency, where cessation of aspirin in participants taking it at study entry appeared to be safe.

Again, the FAVOURED TMC gratefully acknowledges your efforts to actively screen more patients in this study. We can improve the recruitment rate dramatically by not excluding all the patients who are on aspirin at screening.

We encourage everybody to scrutinise the indications for aspirin treatment and make decisions informed by the evidence and by what you feel is in the best interests of your patients.



Changes to the Study Protocol and Case Report Forms

The Safety and Data Monitoring Committee (SDMC) for the FAVOURED study met for the first time in October 2009 and discussed various aspects of the study. One key issue that was discussed at this meeting was the reporting of the event rates and stopping rules for the study.

As a result of these discussions, it was decided to revise the study protocol to both ensure that there is no ambiguity with the information required to analyse the outcome measures and clarify certain aspects of the data to be collected.

In line with these changes, the electronic Case Report Forms (eCRF) using InForm™ system will also be updated. These changes, with suitable explanation within the updated Operations Manual, will hopefully reduce some of the confusion experienced by site staff when reporting key study events such thromboses or interventions with relation to the study AVF.

None of the proposed changes will affect patient care, ie there are no changes to the patient information, consent or the lifestyle questionnaire, so hopefully the ethics amendment process will be straight forward.



For Further Information :

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Questions from Sites

Q: Are the patients supposed to take any of the FAVOURED Study medications the morning before theatre?

A: The decision for patients to take medication on the morning of surgery is at the discretion of the treating physician and in line with the standard procedure at the site ie if patients routinely take their other medication on the morning of surgery, then they should also take their FAVOURED Study medication.



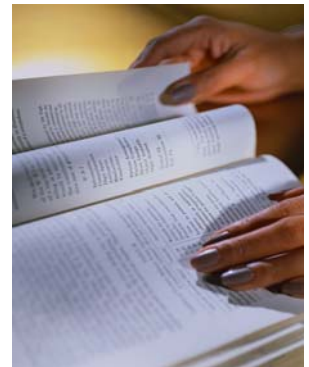
Q: If a patient has elected to have Peritoneal Dialysis but have had an AVF inserted at the same time as the Tenckhoff Catheter – Are these patients suitable to participate in the study?

A: As discussed earlier in the year with sites and as a part of the latest update of the study protocol, the inclusion criterion “Currently on haemodialysis or haemodialysis is planned to start within **6 months**” has been changed to “Currently on haemodialysis or haemodialysis is planned to start within **12 months**”. This will allow patients who commence dialysis using PD more time to move to HD. This change to the inclusion criteria reflects the addition of extra outcome measure “Functional Patency at 12 months”

Monitoring

A total of 15 sites have now had at least one monitoring visit. These sites include Austin Health, Monash Medical Centre, Concord, Fremantle, Gold Coast, Princess Alexandra, Royal Melbourne, Royal Perth, Royal Prince Alfred, Sir Charles Gairdner, Royal Adelaide, The Queen Elizabeth, John Hunter and Toowoomba Base Hospitals.

There have been no major issues that have arisen during monitoring with all sites having done a great job. For remaining sites, monitoring will be organised as soon as sites have recruited one or two patients.



Fishy Humour

Two mad keen fishermen go out on a sub-freezing winter's day. They cut a hole in the lake, bait their hooks and throw the lines in.

They wait. An hour passes. Nothing.

Two hours pass. Still, not even a nibble.

The two men, nearly frozen stiff and very disappointed, are about to leave.

Then a small boy cuts a hole not far away. The two men watch as he tossed in the line. They shake their heads. But, almost immediately, the boy pulls out a fish. Fluke, says one man to the other.

After a few minutes, the boy has another fish. Then another. Then another. And so on.

The two men's disappointment turns to jealousy and bewilderment. They walk over the boy, still reeling in fish at an amazing rate.

"Hey kid" says one man. "We've been freezing out bums off for two hours without a nibble. How come you're getting all those fish?"

The boy mumbles something in reply.

"Speak up kid, I can't hear you".

The boy covers his mouth with his hand then, after a few seconds, turns to face the men. The boy says "You gotta keep the worms warm".

