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AUSTRALASIAN
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AUSTRALASIAN KIDNEY TRIALS NETWORK

FAVOURED Newsletter

Season Greetings from FAVOURED Study

After a slow start to the year, last half of 2011 has been a very busy for the FAVOURED Study.

All members of the Trial Management Committee, Mike and myself would like to thank everybody for their extremely hard work throughout this year. This includes all staff involved in the study at sites, the representatives from Abbott and Bayer for their assistance with organising the study medication and our overseas coordinators, who are Derby R & D in the United Kingdom and Klinssel in Malaysia.

I hope that everybody has a Joyous Christmas and an Wonderful New Year.

Cheers

FAVOURED Project Manager

Peta-Anne Paul-Brent



Abbott Products Bridging Grant



In November, we received the fabulous news that Abbott Products, the company that has kindly provided the Omacor (fish oil) capsules over the last 4 years. was granting us \$200,000 over 2 years to assist with the completion of the study. This money will be mainly be directed into patient capitation and salaries.

We are also applying for additional funding from the NHMRC project grant scheme and Bupa Foundation.

New Clinical Research Associate—Dr Mike Watson

Mike started with the AKTN mid-2011 as a Clinical Research Associate for the FAVOURED and AVATAR Studies. He received his PhD from Monash University, Faculty of Medicine in 1995.

He has worked as a research scientist at the University of Queensland, University of Southern Queensland and the University of Oxford looking at new pharmacological treatments for chronic pain and Duchenne Muscular Dystrophy. Mike has also worked in Australia and the Caribbean teaching medical students renal and cardiovascular physiology.

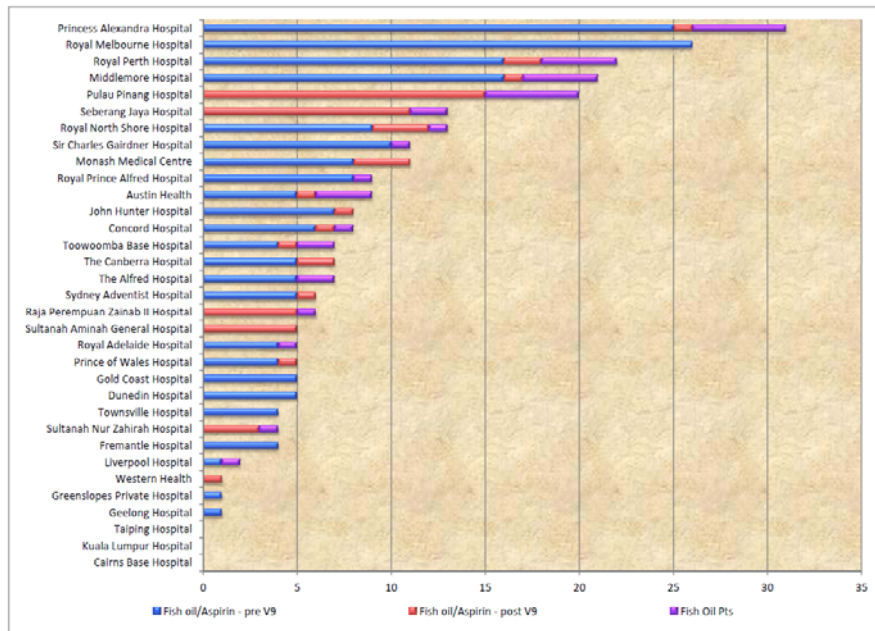


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Site Recruitment Status

Overall, we have a total of 277 patients, 29% of the total recruitment target of 950.



We now have sites actively recruiting in Australia (24 sites), New Zealand (2 sites) and Malaysia (7 sites). In ANZ, our newest active site, Western Health, has recruited their first patient. Royal Melbourne Hospital is currently not recruiting for the study but we are hoping that they will be able to rejoin the study at a later stage.

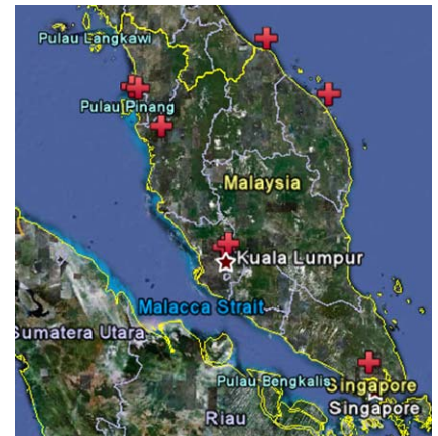
Princess Alexandra Hospital is still our overall highest recruiter with 31 patients with Royal Perth Hospital second with 22 patients. A special mention goes to our 2 top Malaysian recruiters, Pulau Pinang and Seberang Jaya Hospitals with enrolments of 20 and 13 patients respectively

Since the restart of recruitment in August 2011, our average monthly recruitment rate has been 18 patients. To finish recruitment for the study within 12 to 18 months, we need to increase our recruitment to 30 pts per month. We will be assisted in this target with the introduction of the UK sites in early 2012 and the continued support of our current sites.

Malaysian Sites

In March of this year, Dr Carmel Hawley and Peta-Anne Paul-Brent travelled to Kuala Lumpur for the Initiation meeting for the Malaysian Sites. The meeting included a total of 19 participants from all 8 sites with the addition of staff from Klinsel Sdn Bhd who will be coordinating the study in Malaysia.

Malaysian sites started recruitment at the beginning of August and have already enrolled 48 patients. For the 2 top recruiting sites, this means they are recruiting more than one patient per week. Well done to all Malaysian sites for this awesome effort.



United Kingdom Sites

The central ethics and governance approval progress is well advanced. We have ethical approval for Version 9 of the study protocol and been adopted onto the National Institute for Health Research Portfolio. The NIHR Portfolio is a database of high quality clinical research studies that are supported by the NIHR Clinical Research Network. Studies adopted by the NIHR portfolio qualify for NIHR clinical research network infrastructure funding which fund research nurse positions.

We have just received approval for the Clinical Trial Authorisation from the MHRA. Outstanding issues are governance approval at sites including the CTAs and the packaging of the study medication for the UK sites.

We are aiming to have the first sites started in January.

FISH Study Report

Dr. Charmaine Lok from the University of Toronto presented the results of the FISH trial (Fish oil in inhibition of stenosis in haemodialysis grafts) at the 2011 ASN Annual Scientific Meeting in Philadelphia.

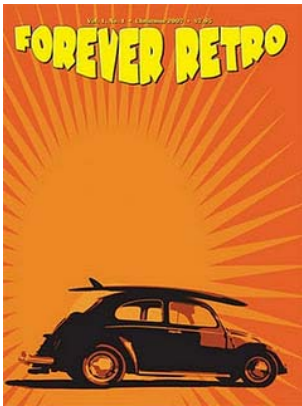
In this study, a total of 201 adult haemodialysis patients were randomised to receive 1g of fish oil or placebo after 7 days of creation of arteriovenous graft (AVG). Duration of follow up was 12 months and the primary outcome was native patency, defined as patency without a radiological or surgical intervention, or thrombosis.

There was no difference in the primary outcome between the 2 groups (loss of patency 48% and 62% in the fish oil and placebo groups, respectively, $p=0.064$).

Results of several pre-defined secondary outcomes were favourable for the fish oil group (time to and rate of loss of patency, time to and rate of thrombosis, rate of radiological or surgical interventions, systolic blood pressure, and cardiovascular events).

There were no differences in the bleeding events or other complications between the two groups.

Retrospective Data



With the introduction of Version 9 of the protocol, there was a significant change the data we needed to collect, particularly related to the primary outcome, AVF Access Failure. Over the last 7 months, sites have been diligently collecting and entering this retrospective data for the 184 patient enrolled prior to change in protocol.

The key data to be entered included Central Venous Catheter usage, additional information about reason for AVF abandonment, the timing of the start of Haemodialysis and the 12 HD session during the Cannulation Assessment Period. Currently sites have entered the data for 170 patients.

Currently the estimated pooled event rate (whether a patient's AVF was abandoned, had a thrombosis or was unable to be cannulated during CAP, for up to 12 months) is well above the assumed event rate of 30% used in the sample size calculation.

Changes brought by Protocol V9

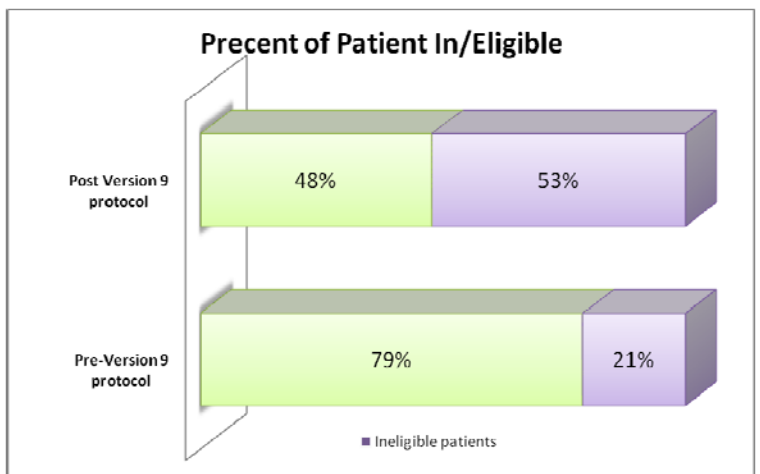
When we changed the inclusion criteria of the FAVOURED protocol to include aspirin taking patients, we had 2 main aims:

- To improve recruitment
- To bring the study cohort characteristics (our patient were younger and healthier) in line with the general renal population

Since August 2011, our recruitment rate has jumped from an average of 8 patients per month to 18 patients per month. This is partly due to the introduction of the Malaysian sites, but also due to more patients being eligible for the study. Screening Log data has shown that 48% of patients were eligible for the study prior to V9, compared with 79% of patients after the introduction of V9, meaning that it should be much easier to now find patients. This is also a reminder of how important it is to maintain site Screening Logs.

Also a review of the baseline characteristics of patients enrolled pre and post V9 protocol, a number of changes were noted. Although the average age of patients stayed the same, the rate of co-morbid conditions such as Type 2 diabetes, ischemic heart disease and congestive cardiac failure increased significantly in the post V9 patients.

Please remember to keep your Screening Log up to date



Questions from Sites

Q: Is it necessary to collect batch samples from remote patient at Weeks 6 and 12?

A: Often the only reason a remote patient is unable to participate in the study is the collection of the batch samples at Week 6 and 12. To allow these patient to be enrolled into the study, the TMC has decided to relax the requirement for the batch sample collection from patients who are unable to attend the visit in person.

These allowances should boost recruitment at certain sites.

Please contact Peta or Mike for further information

The only documentation required is the completion of a Protocol Deviation Log entry (Week X batch samples not collected). Please remember to fax the protocol deviation log to 07 3176 5663 after each log entry.

Q: What is the minimum time between Randomisation and Surgery?

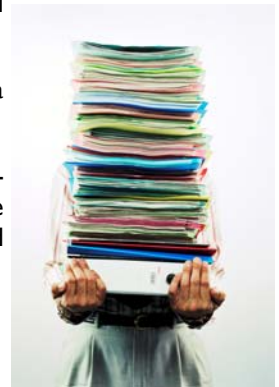
A: The TMC has stated that there should be at least one dosage of the study medication (2 fish oil capsules and 1 aspirin tablet) prior to surgery. This will potentially allow sites to randomise patients on the day of surgery. However, the TMC advises wherever possible, all patients should take the pre-operative medication as prescribed. Please remember that the baseline blood sample must be collected prior to the start of study medication.

Monitoring

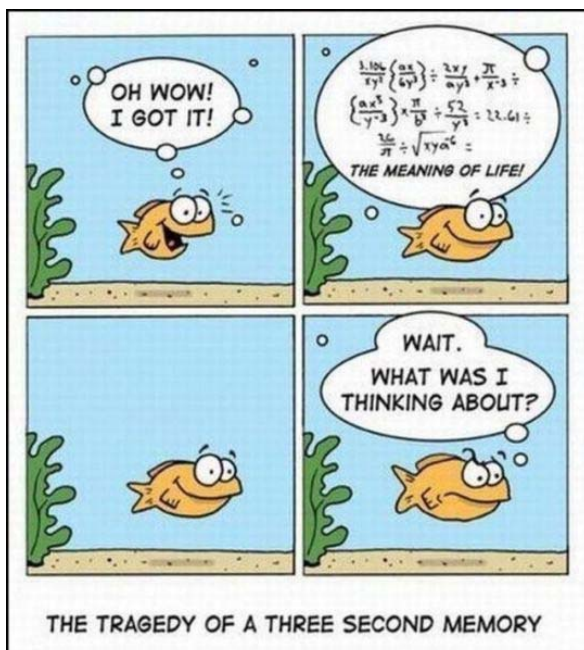
Due to financial constraints and the pause in patient recruitment, site monitoring for the FAVOURED Study was put on hold during much of 2011, with only 10 sites visited by Peta and Mike in ANZ. Klinsel is handing all monitoring for Malaysian sites.

There have been no major issues that have arisen during monitoring with all sites having done a great job.

On-site visits will continue next year but will be supplemented with remote monitoring which involves the AKTN Staff reviewing InForm data to ensure that it is logical and complete. Sites will be made aware of any issues that occur during remote monitoring via Open Queries in InForm (Red Traffic Lights) and/or a list of issue emailed to site staff.



Fishy Humour



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