



AUSTRALASIAN
KIDNEY
TRIALS
NETWORK

Australasian Kidney Trials Network NEWSLETTER

No.3, November 2006

Message from the Chairs

Welcome to the third newsletter of the Australasian Kidney Trials Network (AKTN).

The last year has been an exciting one for the network. Three trials have now progressed to the stage where we plan to commence them in 2007. These will be presented at the upcoming DNT meeting in March. More details can be found later in the newsletter or are available on our website.

We are pleased to announce that one of these trials, led by Dr. Ashley Irish, has been successful in obtaining a National Health and Medical Research Council project grant of almost \$1.8 million. The Chief Investigators on the grant, from Perth, Melbourne, Sydney and Brisbane, represent a broad collaborating group of researchers planning to investigate the role of aspirin and fish-oil in preventing fistula thrombosis.

We would also like to thank all the people who attended the AKTN educational program held prior to the ANZSN and RSA conference in Melbourne earlier this year. This program, attended by 45 participants, provided a broad introduction to several facets of clinical research including design, management, randomization, sample size calculation and ethics and regulatory issues. We are currently considering several options for our 2007 educational initiatives; including an intensive protocol development course, or alternatively, a trial co-ordinator orientated course.

Please remember that the network is always seeking submissions of trial concepts from individuals or groups interested in progressing research in nephrology. If you have any questions about how to submit and develop ideas for clinical trials, please contact the AKTN secretariat.

We would finally like to thank you all for your support so far, and we look forward to working with you all as we get trials underway in the new year.

Best wishes,

Alan Cass

Carmel Hawley

AKTN website

A great source of information about the network is our website (www.aktn.org.au). Here you will find information on network procedures, policies and events, as well as downloadable forms for the submission of trial ideas.

We are currently endeavouring to upgrade the website so if you have any additional information or services that you would like included on the site please don't hesitate to let Daniel Francis know at d.francis@uq.edu.au.

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NHMRC Grant Success

The AKTN has received nearly \$1.8 million dollars to conduct the trial entitled, 'Randomised, placebo-controlled, double blind, factorial design study of fish oil and aspirin in the prevention of early vascular access thrombosis' on behalf of the Australian and New Zealand Society of Nephrology.

The trial now known as FAVOURED (Fish oil and Aspirin and Vascular Outcomes in Renal Disease) was developed and managed by a steering group (listed below) who will be working to progress the trial quickly for an anticipated start in early 2007.

Previously we have sent a small feasibility questionnaire to Heads of Units and would invite those units yet to respond to complete this and forward it to Daniel Francis at d.francis@uq.edu.au

We hope to announce further study details and timeline by December 2006.

Trial Management Committee

Dr Ashley Irish	Royal Perth Hospital
Dr Alan Cass	The George Institute for International Health, Sydney
Dr Sharan Dogra	Royal Perth Hospital, Perth
Elaine Beller	University of Queensland, Brisbane
Ass Prof Carmel Hawley	Dept of Nephrology, Princess Alexandra Hospital,
Ass Prof Peter Kerr	Department of Nephrology, Monash Medical Centre,
Dr Trevor Mori	School of Medicine and Pharmacology, University of Western Australia, Perth
Dr Kevan Polkinghorne	Department of Nephrology, Monash Medical Centre,
Dr Amanda Robertson	Department of Nephrology, Royal Melbourne Hospital,
Brenda Rosser	University of Queensland, Brisbane

Work with the AKTN—Data Manager needed

The AKTN is currently seeking to employ a full-time Data Manager. The successful applicant will be required to undertake data management tasks for a large multi-centre Randomised Controlled Trial and other trials as part of the activities of the Australasian Kidney Trials Network.

This is a full-time, fixed term appointment for 3 years at HEW Level 6. The remuneration package will be in the range of \$60,025 to \$64,682 per annum including employer superannuation contributions of 17%. Level of appointment will be commensurate with qualifications and experience. The position is based at the Princess Alexandra Hospital in Brisbane.

A full position description, including details for applying can be found on seek.com (<http://seek.com.au/jobsearch/index.ascx?AdvertiserID=21775730>). If you have any queries, or are interested in this position please do not hesitate to contact Brenda Rosser (email: b.rosser@uq.edu.au, ph: (07) 3240 613). The closing date for applications is 20th of November however please contact Brenda Rosser if you would like an extension.

New Staff

Brenda Rosser has recently joined the AKTN secretariat as a full time Data Manager. Her experience in the practical conduct of trial management has already proved invaluable as we look to begin running trials in 2007.

Brenda started her working life in medical laboratories, ranging from a small country pathology service to specialised labs including red cell serology. She also has 5 years human resources experience in a health care setting. More recent positions have included research administration and support, as well as experience as an oncology data manager. This included working on a range of single and multi centre clinical trials ranging from investigator initiated studies to monitored pharmaceutical trials. Brenda's current role as data manager with the Australasian Kidney Trial Network will involve establishing trial infrastructure and assisting with the development and conduct of new trial proposals.

Trials - at initiation stage

These three trials have been developed by the network to a stage where recruitment will begin in 2007. Further information including trial schemas and questionnaires for interested sites are available from our website at www.aktn.org.au

Fish oil and Aspirin in Vascular access Outcome in REnal Disease (FAVOURED)

Led by Dr. Ashley Irish from Royal Perth Hospital, this study aims to determine whether the use of the anti-platelet agents aspirin and fish oil, either alone or in combination (in a factorial design), will effectively reduce the risk of early thrombosis in de novo arterio-venous fistulae (AVF). The study population is patients with stage IV or V chronic kidney disease (CKD) who require or will require haemodialysis, are scheduled to undergo creation of an AVF and are not currently taking anti-platelet agents. The primary outcome is patency of the AVF at three months after randomisation. Other outcomes include functional patency at six months, primary patency time, secondary (assisted) patency time, and adverse events, particularly bleeding. We have recently been successful in obtaining funding to conduct this trial and so will be looking to commence recruitment in early 2007. Should you be interested in obtaining further information about this study, please do not hesitate to contact Brenda Rosser (b.rosser@uq.edu.au), or Dr. Ashley Irish (Ashley.Irish@health.wa.gov.au).

Trial Management Committee: shown on opposite page

A randomised, controlled trial of exit site application of Medihoney™ Antibacterial Wound Gel for the prevention of catheter-associated infections in peritoneal dialysis patients

This study will determine whether daily exit site application of standardised antibacterial honey (Medihoney™), in addition to daily cleansing, effectively prevents exit site infections, tunnel infections and peritonitis in peritoneal dialysis patients compared with topical mupirocin prophylaxis of nasal staphylococcal carriers. As a result of feedback from our questionnaire, the requirement for standardised exit site cleaning with chlorhexidine has been dropped and trial patients will follow usual local cleaning protocols. Of all trials under development, this trial is logistically the easiest to conduct. Our preliminary survey of centres suggests that this question is of widespread interest and we look forward to fostering a collaborative approach in the conduct of this trial, which will commence in early 2007. If you have any queries please contact Brenda Rosser (b.rosser@uq.edu.au) or Prof. David Johnson (David.Johnson@health.qld.gov.au).

Trial Management Committee: Prof. David Johnson, Ms. Elaine Beller, Dr. Janak de Zoysa, A/Prof Carmel Hawley, Dr. Steven McTaggart, Dr. Geoffrey Playford, Ms. Brenda Rosser, Dr. Paul Snelling

A randomised, placebo-controlled trial of oxpentifylline on haemoglobin levels in patients with erythropoietin-resistant anaemia.

The study aims to determine if the administration of oxpentifylline will effectively treat erythropoietin- or darbepoietin-resistant anaemia in chronic kidney disease patients. The study population is adult patients with stage IV or V chronic kidney disease (CKD) (including patients on dialysis) with significant anaemia ($Hb \leq 110$ g/L) for at least 3 months that is unresponsive to large doses of either erythropoietin (200 IU/kg/week) or darbepoietin (31 mg/kg/week) and for which there is no clear identifiable cause. The primary outcome is haemoglobin level at four months after randomisation. Other outcomes include changes to the dosage of erythropoietic stimulatory proteins, changes to Key's index, changes to blood transfusion requirements and adverse events.

Given that resistance to erythropoietin is uncommon, we are currently investigating potential collaboration with overseas centres, however we are very keen to recruit as much as is possible from within Australasia. If you would like to be involved in this trial, and have not yet filled out a questionnaire please go to our website and download a copy, or contact either Brenda Rosser at b.rosser@uq.edu.au or Professor David Johnson (David.Johnson@health.qld.gov.au).

Trial Management Committee: Prof. David Johnson, Ms. Elaine Beller, Dr. Rob Fassett, A/Prof Carmel Hawley, Dr. Alan Cass, Dr. Stephen McDonald, Ms. Brenda Rosser, A/Prof Rowan Walker

AKTN Trial Development

The AKT Network seeks to facilitate the conduct of high quality clinical trials in kidney research. To ensure that trials are developed to the high standard expected of the AKT Network, that they are clinically relevant, that trials and trial proposers are treated fairly, and that AKT Network resources are spent in the most efficient means possible, a trial approval process has been developed. The process for an AKTN coordinated trial is shown graphically in the figure below.

As can be seen there are three phases to the process. At the Concept Phase preliminary information on a trial idea is submitted to the Network with the Scientific Committee voting on whether or not this idea should be pursued. The idea of this phase is to avoid enormous amounts of time and resources being invested into a trial that has little chance of being accepted for initiation. The Development Phase involves the development of a full protocol. Based on this, the Scientific Committee will then decide on whether the trial is to go ahead. An approved trial then moves into the Initiation phase when the trial is conducted. More details of this process can be found on our website.

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Trial Approval Process

