

NEWSLETTER

No. 5, June 2008

Message from the Chairs

Welcome to the fifth newsletter of the Australasian Kidney Trials Network (AKTN). The past 12 months has seen a period of growth on many levels for the AKTN with the commencement of both the HONEYPOT and FAVOURED trials and the employment of new staff members. Our new Executive Officer, Melissa Gardiner commenced on the 3rd of March. We also welcome Conrad Leonard who commenced work at the same time with the Queensland Clinical Trials Centre as Coordinating Data Manager. Part of his role is to support AKTN in the web based data management activities. Unfortunately Brenda Rosser left the AKTN in March to commence a new role in oncology and we are grateful for her efforts in ensuring that the HONEYPOT and HERO studies are well on their way to being successful projects and wish her all the best in her career.

The role as study coordinator for HONEYPOT and HERO was filled by Alicia Smith who commenced with the AKTN on the 21st of April. In addition we have recently recruited a Study Coordinator for the BLOCADE trial, Fiona Rogers and a Central Study Coordinator, Alison Martin.

Three of the four planned Special Interest Groups have been formed in Haemodialysis (chaired by Maggie Fisher), Transplant (chaired by Josette Eris) and Chronic Kidney Disease (chaired by Gopi Rangan). We have tried to establish a balance of experienced and developing career researchers within each group. The goal of these groups is to develop new trial ideas and maintain long term group involvement in the trials. Special Interest Group Chairpersons will be reporting on their activities and presenting ideas to the Scientific Committee.

The next couple of months should prove an exciting time with the commencement of all three active trials and the successful establishment and functioning of all Special Interest Groups.

Best wishes,



Assoc/Prof Alan Cass



Assoc/Prof Carmel Hawley

Scholarships

The AKTN provides scholarships for individuals wishing to conduct PhDs or Masters by undertaking research in conjunction with the AKTN. A number of scholarships are available each year. Two scholarships are available through funding provided by the University of Queensland (UQ) with candidates required to be enrolled, or to enrol, in a PhD through UQ. A third scholarship will be available to a successful candidate in Australia or New Zealand and can be enrolled at the University of his/her choice.

Applicants may be intending to study part time or full time and may potentially combine their study with clinical appointments. Health workers other than medical graduates such as nurses, scientists, and allied health professionals, are also invited to apply for these scholarships.

For more information please contact Melissa Gardiner at m.gardiner@uq.edu.au or 61 7 3240 6133.



**A randomized controlled trial evaluation of antibacterial HONEY versus Nasal Eradication of staphYlococci for the Prevention Of Tenckhoff infections in PD
(ACTRN12607000537459)**

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

Following our recent success in obtaining a Queensland Government Smart State award (\$432,400 over 3 years), a Baxter Extramural grant (\$US375,000 over 3 years) and a payment from Gambro (\$5,000), the HONEYPOT trial is now fully funded. We have recently placed our first Medihoney™ Antibacterial wound Gel order and the web-enabled data management site is fully functional. In addition we have now have eight sites that are fully operational with signed Clinical Trial Agreements (CTAs), ethics approvals and NATA lab accreditation (Launceston General Hospital, Queen Elizabeth Hospital, Royal Adelaide, The Princess Alexandra, Monash Medical Centre, Royal Perth, Royal Children's Hospital) with more expected to follow in the near future. We would like to thank Brenda Rosser for her early work in ensuring the trial was successful and Sabine Sand for her efforts and enthusiasm in taking care of all our legal matters. In addition we would like to thank the AKTN staff who have been involved in pushing this study towards commencement including Alicia Smith, Peta-Anne Paul-Brent, Melissa Gardiner, and Conrad Leonard.



**Fish oil and Aspirin in Vascular access OUTcomes in REnal Disease
(ACTRN12607000569404)**

Trial Management Committee: Dr Ashley Irish, A/Prof Alan Cass, Dr Sharan Dogra, Ms Elaine Beller, A/Prof Carmel Hawley, Prof Peter Kerr, Dr Trevor Mori, Dr Kevan Polkinghorne, Dr Amanda Robertson, A/Prof Johan Rosman, Ms Peta-Anne Paul-Brent

The FAVOURED Trial is progressing well and looks set to commence recruiting by the end of June. The study medication has now been packed and sent to Cryosite for storage and distribution. We currently have 6 sites with full ethics and CTA approval with another 12 sites with ethical approval. The sites that are ready to go include Toowoomba Base Hospital, Royal Melbourne Hospital, Launceston General Hospital, Princess Alexandra Hospital, Royal Perth Hospital and The Queen Elizabeth Hospital. There has been a slight delay the production of the electronic Case Report Forms (eCRF) but this will not delay recruitment as we will be using paper CRFs till the eCRF is up and running. Over the last month we have been holding study coordinator meetings in Sydney, Melbourne and Auckland to review the study procedures of both the HoneyPot and Favoured Studies. These meetings were found to be particularly helpful for new staff who did not attend the initiation meeting in September 2007.



**Haemoglobin levels in patients with Erythropoietin-Resistant anaemia treated with Oxpentifylline
(ACTRN12608000199314)**

Trial Management Committee: Prof David Johnson, Ms Elaine Beller, Dr Rob Fassett, A/Prof Carmel Hawley, A/Prof Alan Cass, Dr Stephen McDonald, Miss Alicia Smith, A/Prof Rowan Walker, Dr Genie Peggadogos

The main hypothesis of the study is that Oxpentifylline (Trental®) administration will effectively treat erythropoietin- or darbepoietin-resistant anaemia in chronic kidney disease patients. The main inclusion criteria are adult patients with stage 4 or 5 chronic kidney disease (CKD) (including patients on dialysis) with significant anaemia for at least 3 months that is unresponsive to large doses of either erythropoietin or darbepoietin and for which there is no clear identifiable cause. This trial will commence in the second half of 2008. We have been successful in obtaining \$112,000 from Amgen to conduct this study in addition to \$192,820 from a Roche RoFAR grant. We have obtained Oxpentifylline from Sanofi-Aventis and have negotiated with a Brisbane based company regarding the production of a placebo. We expect CTAs to be sent to all interested sites by the end of June with a hopeful commencement some time in September in 2008.

Early stage trials in development - UPDATE



Beta-blocker to Lower Cardiovascular Dialysis Events

Trial Management Committee: Dr Matthew Roberts, A/Prof Frank Ierino, Prof Henry Krum, Ms. Elaine Beller, A/Prof Carmel Hawley, A/Prof Alan Cass, Dr Nicole Isbel, Miss Fiona Rogers, Dr Helen Pilmore, Prof Andrew Tonkin

This study aims to determine whether beta-blocker therapy with carvedilol will reduce the cardiovascular morbidity and mortality of high-risk patients receiving dialysis. As a first step however, a feasibility and tolerability Vanguard study is being planned. The study population for this trial will be patients over 50 years of age, or patients with either diabetes or documented cardiovascular disease. The primary outcome for the planned hard end-points study will be a composite of cardiac death, non-fatal myocardial infarction, admission for tachyarrhythmia and coronary revascularization. The aims of the Vanguard study will be to determine recruitment rates, tolerability of carvedilol and event rates for the primary end-point parameters.



A TRANS-tasman DIABetes study

*Principal Investigator: Dr Helen Pilmore
Study Investigators: Dr Scott Campell, Dr Josette Eris,
Dr John Kanellis, Dr Kate Wyburn*

Two individual trials are being considered as part of the Transdiab trial development.

Study A: A randomised double blind placebo controlled trial of metformin versus gliclazide in new onset diabetes (NODAT) following renal transplantation.

Study B: A randomised double blind placebo controlled trial of metformin versus placebo in patients with impaired glucose tolerance after renal transplantation.

The development of new onset diabetes (NODAT) after renal transplantation is a common clinical problem. Diabetes after transplant has been associated with increased acute rejection, increased cardiovascular death and increased all cause mortality. In addition, it is a likely contributor to chronic allograft nephropathy. There are no studies examining the optimal treatment for diabetes after renal transplantation. Current practice in Australia and New Zealand favours commencement of either a sulphonylurea or insulin in patients with NODAT. Metformin is not extensively used because of concerns regarding lactic acidosis in patients with renal impairment, although recent data does not support the association of lactic acidosis with this drug in renal impairment. Metformin however, is the only agent that has been shown to reduce all cause mortality in patients with DM and heart failure. In addition, Metformin has been shown in a large meta-analysis to result in a reduction in all-cause mortality and diabetes related complications in obese patients compared to sulphonylureas and insulin. Moreover, patients treated with metformin mono-therapy had benefits in terms of glycaemic control, body weight, dyslipidaemia, and diastolic blood pressure. We propose a 2 part RCT studying the role of Metformin in the treatment of New Onset Diabetes Mellitus (Substudy A), or impaired glucose tolerance (Substudy B) after renal transplantation.



CANnulation with BUTTONhole versus rope ladder

Trial Management Committee: Dr Maggie Fisher (Chair)

A fundamental requirement for haemodialysis is the establishment of vascular access with the Arterio-venous fistula (AVF) as the preferred access type. Over a period of time the veins develop enabling cannulation for haemodialysis using large dialysis needles (14g to 17g). Historically, there has been a principle of rotating needle sites to avoid aneurysm formation at the AVF cannulation sites. This is supported by KDOQI and CARI guidelines. A second cannulation technique called the "Buttonhole" technique has been reported in the literature but has been less widely used. This technique involves the use of the same site each dialysis over a period of weeks resulting in the development of a tunnel. The proposed benefits of the "buttonhole" technique include a lower non-infectious complication rate and ease of cannulation. No randomised controlled trial (RCT) addressing the multiple measures below has been undertaken to compare buttonhole technique and site rotation. Thus, the aim of this study is to explore the outcomes of two vascular access cannulation techniques –Buttonhole vs Site Rotation.

New Staff



Dr Melissa Gardiner—Executive Officer

Melissa Gardiner joined the Australasian Kidney Trials Network (AKTN) in March 2008 as Executive Officer. She has a Bachelor of Biotechnology Degree (Hons) from Flinders University of South Australia and a PhD from the Institute for Molecular Biosciences at the University of Queensland. Before joining the AKTN she worked as a postdoctoral research scientist at the Queensland Brain Institute.



Dr Conrad Leonard—Coordinating Data Manager

Conrad Leonard joined the Queensland Clinical Trials Centre (QCTC) as Coordinating Data Manager in March 2008. Conrad has a BSc and PhD in theoretical physics from the University of Melbourne and he has worked in academia and the IT industry, made pizzas, washed dishes and welded steel plates, and has realised that no matter what you do, at least 50% of the quality of your work experience is determined by the relationships you have with your workmates, so look after them.



Miss Alicia Smith—HONEYPOT and HERO Study Coordinator

Alicia completed a Bachelor of Science with honours in physiology at Adelaide University. She was involved in conducting faecal occult blood test (FOBT)-based bowel cancer screening research studies for 5 years, during which she completed her Masters degree in Public Health. 18 months ago Alicia moved to Brisbane and began working for the National Bowel Cancer Screening Program, as the Qld Information Manager. After deciding to pursue a career in clinical trials, she started working as a Trials Coordinator for the AKTN on the 21st April, 2008.



Miss Fiona Rogers—BLOCADE Study Coordinator

Fiona completed Bachelor of Science (Neurobiology/Physiology)/Bachelor of Arts (Psychology) double major at the University of Queensland in 2002. She then completed her honours in 2003 in the School of Biomedical Sciences at the University of Queensland. In 2004 she began working at the Queensland Brain Institute as a Research Assistant. Prior to commencing at the AKTN, Fiona was employed at the Queensland Brain Institute as a Senior research assistant and Lab manager for Professor Perry Bartlett. Fiona commenced working as a Trials Coordinator for the AKTN on the 2nd of June 2008.



Ms Alison Martin—AKTN Central Study Coordinator

Alison obtained a Bachelor of Nursing Science from James Cook University, Townsville in 1994 and completed a Graduate Certificate in Critical Care at Queensland University of Technology in 1998. Prior to commencing at the AKTN, Alison was employed as the Nurse Unit Manager, in the Department of Nephrology at Princess Alexandra Hospital where she managed a clinical trials unit and coordinated all Queensland sites participating in a large multi-centre, Investigator driven trial. Alison commenced as Central Study Coordinator at the AKTN in the beginning of June 2008.

Contact us

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