

NEWSLETTER

No. 7, December 2009

Message from the Chairs

Welcome to the seventh newsletter of the Australasian Kidney Trials Network (AKTN). As 2009 draws to a close, we would like to take the opportunity to thank all those involved with the Network over the past year. The AKTN has continued to flourish, with an employment of a full complement of staff and three of our trials actively recruiting patients.

We would like to thank all our Operations staff for their hard work and dedication throughout the year. In addition we would like to welcome Liza Vergara as the new BLOCADE and HONEYPOT Project Officer and Donna Reidlinger as the new HERO and PEXIVAS Project Officer in place of Alicia Smith who has moved into a Project Management role. It is also important to acknowledge the effort and support of all Investigators, TMC members and Study Coordinators at participating sites.

In early December, we were unfortunate to lose our Coordinating Data Manager, Conrad Leonard, however we would like to take this opportunity to thank him for all his tireless efforts and wish him every success for his future.

On behalf of all AKTN staff we would like to wish you all a very merry Christmas and a safe and Happy New Year!

Best wishes,



Assoc/Prof Carmel Hawley
Chair, Operations Secretariat



Prof Alan Cass
Chair, Scientific Committee

MERRY CHRISTMAS



Highlights for 2009



ANZSN, Hobart September 2009

In September 2009, the Australian and New Zealand Society of Nephrology's (ANZSN) Annual Scientific Meeting was held in Hobart. The AKTN proudly exhibited at this conference and achieved much interest participation from conference delegates. The AKTN hosted a lunch session to highlight the current trial status of the AKTN which was received well by all those who attended. In addition, the AKTN presented in the main program and excellent attendance and responses were achieved for this session.



AKTN joined the Centre for Kidney Disease Research in the School of Medicine

In December 2009, the AKTN became a division within the Centre for Kidney Disease Research located within the School of Medicine at the University of Queensland. We are excited at this new venture and strongly believe this change will assist us in achieving our strategic aims and goals in the coming years.



Funding secured in 2009

This year was an extremely successful year for the AKTN with the extension of the NHMRC Enabling Grant (\$2 million over the next 5 years). In addition, the PEXIVAS trial which is to be coordinated through the AKTN, was successful in securing an NHMRC project grant (through Dr Chen Peh and the University of Adelaide) and the Lanthanum trial was successful in securing an unrestricted grant to the value of \$1.5 million over 3 years (through Dr Genie Pedagogos and Shire). Despite our recent success, we are continually seeking additional funding for our current trials so if you are interested in becoming financially involved with the AKTN, please contact our Business Development Manager, Melissa Bruce (melissa.bruce@uq.edu.au) for further information.



Scholarships

AKTN scholarship applications have closed for 2009 and will be announced in the first week of January. We would like to wish all applicants success and advise future applicants that we will be readvertising the Scholarships in August 2010.



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, Prof Alan Cass, Mr Charles Thompson, Dr Janak de Zoysa, A/Prof Carmel Hawley, Dr Steven McTaggart, Dr Geoffrey Playford, Miss Alicia Smith, Dr Liza Vergara, Dr Paul Snelling, A/Prof Vlado Perkovic, Dr Carolyn Clarke

The HONEYPOT Trial is proceeding very well, with most sites successfully recruiting patients, and 58% of the total recruitment target already achieved. There are now 23 sites actively recruiting with total number of patients recruited is 216. Princess Alexandra Hospital has enrolled the most patients to date (32 patients), followed by Dunedin Hospital and The Queen Elizabeth Hospital with 16 patients each. We congratulate the following sites for meeting or exceeding their original recruitment target: Wollongong Hospital, Princess Alexandra Hospital, Dunedin Hospital, Royal Adelaide Hospital and Liverpool Hospital. We have 2 new sites, Royal Hobart (PI Dr Geoffrey Kirkland and Research Nurse Gail Read) and Mater Children's Hospital (PI Steven Dr Steven McTaggart and Study Coordinator Simone Taylor) who are currently completing their documentation to be able to start recruiting early next year. We are still encouraging all sites not to let their guards down and keep on recruiting (especially incident PD patients!) to be able to reach our target of 370 patients.



Fish oil and Aspirin in Vascular access OUTcomes in REnal Disease

(ACTRN12607000569404)

Trial Management Committee: Dr Ashley Irish, Prof Alan Cass, Dr Sharan Dogra, Mr Charles Thompson, A/Prof Carmel Hawley, Prof Peter Kerr, Dr Trevor Mori, Dr Kevan Polkinghorne, Dr Amanda Robertson, Dr David Voss, Ms Peta-Anne Paul-Brent, A/Prof Vlado Perkovic, Dr David Gracey, Dr Amanda Mather, Dr Chen Au Peh, Dr Hooi Lai Seong, Dr Chris McIntyre, Mr Colin Hutchinson

The FAVOURED Study has moved in some exciting new directions in 2009. There are currently 26 sites in Australia and New Zealand actively recruiting patients with a total of 107 patients enrolled. Site monitoring has been completed at 16 sites with all sites performing well and no major issues. Significant process has been made in the expansion of the study into Malaysia (lead PI Dr Hooi Lai Seong) and the United Kingdom (lead PIs Drs Chris McIntyre and Colin Hutchison) with recruitment anticipated to start in both countries in the first quarter of 2010.



Haemoglobin levels in patients with Erythropoietin-Resistant anaemia treated with Oxpentifylline

(ACTRN12608000199314)

Trial Management Committee: Prof David Johnson, Mr Charles Thompson, Dr Rob Fassett, A/Prof Carmel Hawley, Prof Alan Cass, Prof Stephen McDonald, Miss Alicia Smith, A/Prof Rowan Walker, A/Prof Genie Pegadogos, Ms Donna Reidlinger, A/Prof Vlado Perkovic, A/Prof Carl Kirkpatrick

Since the HERO trial initiation meeting held in November 2008, the trial has made steady progress, despite a few delays involving staff turnovers and study medication availability. The HERO trial now has 6 sites actively recruiting. The total number of patients enrolled is 6, and a further 7 sites are expected to begin screening in the New Year. With a target of 110 patients this trial is now well on its way to a successful 2010.



Beta-blocker to Lower Cardiovascular Dialysis Events

Trial Management Committee: Dr Matthew Roberts, A/Prof Frank Ierino, Prof Henry Krum, A/Prof Carmel Hawley, Mr Charles Thompson Prof Alan Cass, A/Prof Nicole Isbel, Dr Liza Vergara, A/Prof Helen Pilmore, Prof Andrew Tonkin, A/Prof Vlado Perkovic, A/Prof Amit Garg

The BLOCADE Trial aims to investigate whether the beta-blocker carvedilol is effective in reducing the incidence of cardiovascular morbidity and mortality in patients receiving dialysis. The study population will be patients receiving dialysis who are over the age of 50 years, or patients over the age of 18 years who have either diabetes or known cardiovascular disease. Because such a study would require very large patient numbers, a feasibility study is necessary to inform the final design of this study with clinically important endpoints. This feasibility study will be undertaken to determine recruitment rates, tolerability of carvedilol and event rates. The trial will recruit 150 participants and will follow them for 12 months, at which time they will have a final study visit. Funding for this study has been obtained from a successful Jacquot grant application (\$700 000 over 3 years) and Pfizer CVL (\$55,000) and further grant applications will be submitted next year. To date, 11 sites (Australia = 7 sites, New Zealand = 3 sites; Canada = 1 site) have confirmed their participation in the study. Currently, we have 4 sites (Auckland City Hospital, Royal Prince Alfred Hospital, Westmead Hospital and Monash Medical Centre) with ethics approval. We hope to begin recruiting in mid 2010.



ACTIVE Dialysis

Principal Investigator: A/Prof Vlado Perkovic

ACTIVE Dialysis is a prospective, randomised trial designed to provide definitive evidence on the benefits and costs of extending weekly haemodialysis hours beyond current standards funded by a National Health and Medical Research Council (NHMRC) Project Grant. Led by a steering committee of nephrologists and endorsed by the AKTN, the study has received administrative, data management, statistical and infrastructure support from The George Institute for International Health. The primary outcome of the main trial will be the difference in quality of life at 12 months follow up, and a broad range of secondary outcomes will also be assessed. 9 sites from ANZ are now recruiting with more than 10 others (including sites from Canada and the UK) in various stages of preparation. A total of 19 patients have been recruited to date, with a goal of 200 patients to be recruited by December 2011.

Proposed Trials

The TRANS-tasman DIABetes study (Transdiab)

Principal Investigator: A/Prof Helen Pilmore

Recently, the AKTN organised a meeting in Sydney with the Transplant Special Interest Group regarding the TRANSDIAB trial. This trial will study the safety and efficacy of metformin in kidney transplant patients. The trial design and protocol are being developed under leadership of A/Prof Helen Pilmore.

Plasma exchange and glucocorticoids in anti-neutrophil cytoplasm antibody associated systemic vasculitis: a randomised controlled trial (PEXIVAS in Australia)

Principal Investigator: Dr Chen Au Peh

This is a European Vasculitis Study Group (EUVAS) initiated trial that will involve centres in the UK, Europe, USA, Australia and NZ. The Australian and New Zealand component of this trial will be coordinated by the Australasian Kidney Trials Network (AKTN). The aims of this are two-fold: 1) Does the addition of PLEX to cyclophosphamide (CYC) and GC therapy improve the time to the composite endpoint of ESRD or all-cause mortality in severe AAV and 2) Is a low cumulative dose GC protocol as good or better at preventing the composite endpoint of ESRD or all-cause mortality while improving serious infection rates compared to a standard, high dose protocol in patients with severe AAV. The trial has obtained ethical approval for conduct in the UK and US, and applications to ANZ site ethics committees will be submitted early in 2010.

Lanthanum Trial

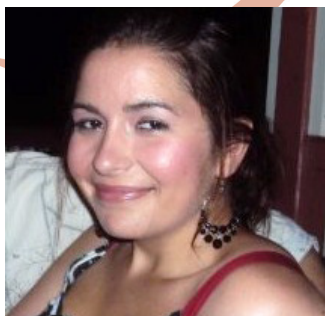
Principal Investigators: A/Prof Genie Pedagogos and Dr Nigel Toussaint

The main objective of the study is to determine whether use of a phosphate binder (lanthanum carbonate) in subjects with Chronic Kidney Disease (CKD) stages 3 and 4 will reduce the risk and burden of cardiovascular disease. Patients with CKD 3 and 4 have a substantially higher incidence of cardiovascular disease contributing to significant morbidity and mortality. Phosphate imbalance is a putative non-traditional risk factor for cardiovascular disease in this population (according to association studies) and lowering serum phosphate levels with a phosphate binder may be associated with reduced morbidity and mortality. The use of lanthanum carbonate to reduce phosphate and calcium-phosphate product may improve arterial compliance and attenuate the development and/or progression of vascular calcification, reduce the incidence of secondary hyperparathyroidism, and potentially reduce the rate of CKD progression.

Interested in participating in a trial?

If you are interested in finding out more information or participating in any of the trials that you have seen advertised, please contact our Project Manager, Alicia Smith (a.smith18@uq.edu.au) for further information.

New Staffing



Miss Shauna McCallion - AKTN Centre Support Officer

Shauna joined the AKTN in December 2009 as the Centre Support Officer. She is originally from Ireland. During her time studying she obtained an Honours Degree in Business Studies Management, a National Diploma in Business Studies and a National Certificate in Business Studies. Shauna has several years experience working as an office administrator in different sectors.

Prof. David Johnson - Deputy Chair AKTN Operations Secretariat

David Johnson is currently the Director of Renal Medicine at Princess Alexandra Hospital, Professor of Medicine and Professor of Population Health at University of Queensland, Chair of the Queensland Statewide Renal Clinical Network, Deputy Chair of the Australasian Kidney Trials Network Operations Secretariat, Chair of the CARI Guidelines Working Parties on Peritoneal Dialysis Adequacy, Evaluation of Renal Function and Management of Early CKD, Chair of the Kidney Check Australia Taskforce, Co-Chair of the Australasian Creatinine and eGFR Consensus Working Party, Co-Chair of the Australasian Proteinuria Consensus Working Party, Founding Member of the NHMRC-endorsed Cardiovascular and Renal Centre of Clinical Research Excellence. Member of the ANZDATA Registry PD Working Group and International Society of Peritoneal Dialysis Councillor. He is the principal investigator on a number of large, multi-centre randomised controlled trials, including the balANZ, HONEYPOT, IMPENDIA and HERO trials. In 2005, he was awarded the TJ Neale Award by the Australian and New Zealand Society of Nephrology for outstanding contributions to nephrologic science. He was a Queensland finalist in the Australian of the Year Awards for 2009.



We have moved!!!!!!!!!!!!!!

Please update your contact details. AKTN staff have moved. Our new address is:

AKTN, School of Medicine
University of QLD, Bld 33, Ground level
Princess Alexandra Hospital, Ipswich Road
Woolloongabba QLD 4102

Our phone numbers have also changed:

Admin office is 61 7 3240 5463
FAX is 61 7 3240 5663

Staff at the AKTN Central Office

A/Prof Carmel Hawley - AKTN Operations Secretariat, Chair
Prof David Johnson - AKTN Operations Secretariat, Deputy Chair
Dr Melissa Bruce - Business Development Manager
Mr Charles Thompson - Biostatistician
Miss Shauna McCallion - Centre Support Officer
Miss Alicia Smith - Project Manager
Ms Peta-Anne Paul-Brent- FAVOURED Project Officer
Dr Liza Vergara - BLOCADE and HONEYPOT Project Officer
Ms Donna Reidlinger - HERO and PEXIVAS Project Officer

Contact us

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