

2009-2010

Annual Report



AUSTRALASIAN
**KIDNEY
TRIALS
NETWORK**

1 July 2009-30 June 2010

TABLE OF CONTENTS

Table of Contents.....	2
The AKTN at a glance.....	3
Message from the Chairs.....	4
2009-2010 Highlights.....	5
Our Governance Structure.....	6
Staff profiles.....	7
Executive Operations Staff.....	7
Operations Staff.....	11
Trials.....	15
Active Trials.....	16
FAVOURED.....	16
HONEYPOT.....	18
HERO.....	20
ACTIVE Dialysis.....	22
Trials under Development.....	24
BLOCADE.....	24
PEXIVAS:.....	26
AVATAR.....	28
IMPROVE.....	30
TransDiab.....	32
CKD-FIX:.....	33
Funding.....	34
Finance.....	37
PhD Opportunities.....	38
Network Staff and Committees.....	39

THE AKTN AT A GLANCE

Our Vision

Our vision for the Network in 2015, is for the AKTN to be a Clinical Research Organisation working with the kidney care community to achieve world class, innovative solutions that make meaningful differences to people with kidney disease. To this end, the Network designs, conducts and supports clinical trials in Australia and New Zealand in conjunction with global collaborators.

Our Mission

To deliver high quality clinical trials to improve the health and well being of people with kidney disease

Our core values

These values guide our individual behaviour, and collectively, our culture and work environment.

1. **Commitment to Excellence**
2. **Working Co-operatively**
3. **Pro-active Leadership**
4. **Commitment to Making a Difference**

Our core strategies

These shared Core Strategies are the steps we will take in order to achieve our Vision and Mission

1. *Facilitate & Promote*
Make it easier and more attractive for the nephrologist community of practise to engage and contribute to clinical research.
2. *Collaborate Internationally*
Collaborate with emerging trials networks in other countries.
3. *Training & Professional Development*
Establish training courses in clinical trials/GCP/Stats/Epidemiology.
4. *High Impact Trials*
Establish high impact multi-centre "wow" trials powered for patient level outcomes.
5. *Build Reputation*
Work towards sustainability.
6. *Build Capability*
Augment career pathways through higher degree research undertaken by medical staff.
7. *Add Value to Evidence*
Successfully completing and publishing existing high impact trials.

MESSAGE FROM THE CHAIRS

The first five years of the Australasian Kidney Trials Network (AKTN) have been an exciting and busy time. We have a number of trials either running, close to initiation or in the development phase. The AKTN has built up local infrastructure in the Operations Secretariat, strengthened by the collaboration between the Brisbane-based and Sydney-based members of the Executive Operations Secretariat, and greatly broadened the available skill sets during this time. We are continuing to forge effective national and international collaborations.

We have had tremendous involvement from the renal scientific community at many levels including as investigators or coordinators, members of Trials Management Committees and /or members of the Scientific Committee or the Special Interest Groups.

This report focuses on the 12 month period from July 2009 – June 2010. We hope you will enjoy catching up with the developments of the AKTN through this report. We value feedback on the progress of this important collaborative group.

The AKTN would like to acknowledge the support received by the University of Queensland, through the Network's position in the Centre for Kidney Disease Research at the School of Medicine. We also acknowledge the tremendous financial and other contributions of the renal community, the Scientific Committee and Advisory Board, our industry supporters and the Australian Government, through the National Health & Medical Research Council (NHMRC).

The next few years will be crucial as in this time we will be completing our first trials, and presenting the results to the international renal community. We will continue to concentrate our efforts on that important goal, and by doing so continue our main focus - to improve treatment options and outcomes for patients with chronic kidney disease.

2009-2010 HIGHLIGHTS

Mid 2010 marks the end of our first period of NHMRC Enabling Grant funding, with our second NHMRC Enabling Grant funding commencing in July 2010. We are pleased to report that over the past 5 years we have been able to establish infrastructure with clinical research governance arrangements for high quality study design, the conduct of clinical trials and data management. Furthermore, the AKTN has been able to successfully leverage competitive funding and has secured funding from the Queensland State Government, Pharmaceutical Companies and Research Foundations. The AKTN's success over this period has been largely due to the invaluable collaboration between the Brisbane-based and Sydney-based members of the Operations Secretariat. Carmel Hawley and David Johnson from the Princess Alexandra Hospital (QLD) and Alan Cass and Vlado Perkovic from the George Institute for Global Health (SYD), have worked tirelessly to ensure the AKTN is a Network representative of the Nephrological community's needs.

While the achievements of the AKTN in its start-up phase have been impressive, the next few years are critical for the Network as the first few trials complete, putting the network on the world stage and in a position where other funding sources are likely to become available. The vision for the future is that we will continue to consolidate our current strengths whilst focusing on further key strategic scientific and operational goals.

A highlight of 2009 was our ability to secure a second round of NHMRC enabling funding which will fund our infrastructure for the period 2010-2015 (\$2 million).

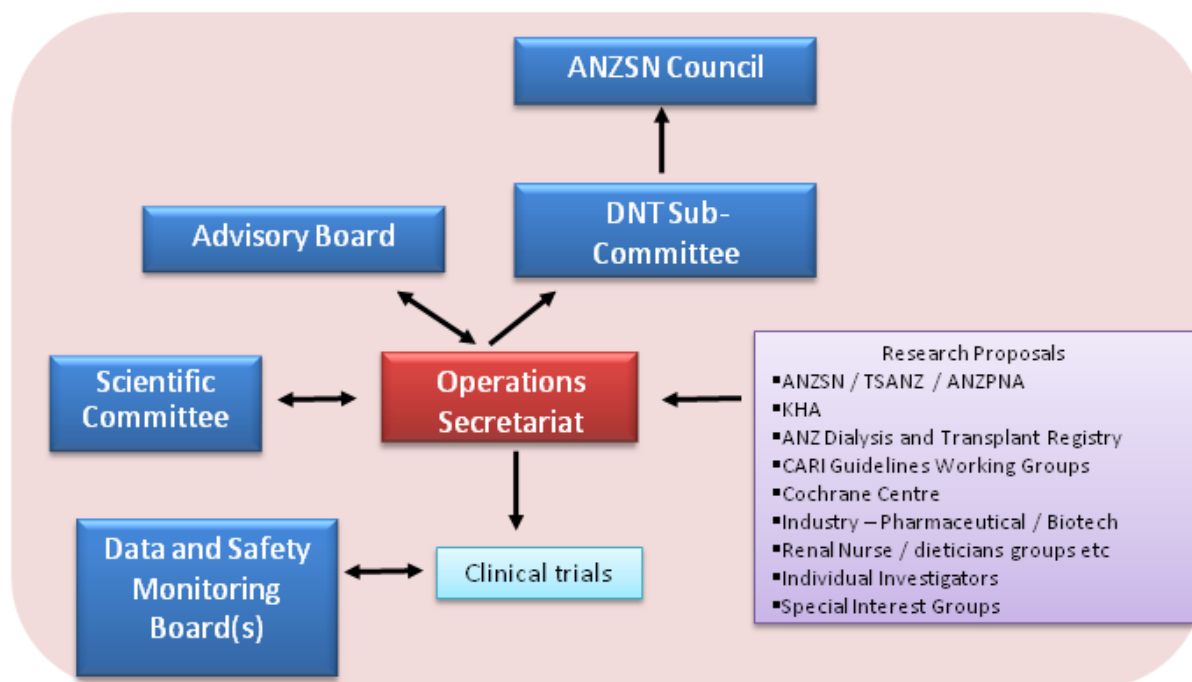
Another exciting change that occurred in late 2009, was the AKTN joining David Johnson's and Glenda Gobe's Centre for Kidney Disease Research (CKDR) in the School of Medicine. The AKTN is very pleased to be remaining within the Faculty of Health Sciences at the University of Queensland, and thanks the School of Population Health for its support over the past 5 years.

In the past two years, the Network has continued to work extremely hard to ensure the continued development of clinical trials, and we are pleased to report that three of our trials are currently actively recruiting. The **HONEYPOT** Trial is now entering its final stages of recruitment, with an additional 89 participants required in the HONEYPOT trial before we reach our recruitment target of 370. The **FAVOURED** Trial is also actively recruiting with a total of 154 patients already recruited at the end of June 2010. We are pleased to announce that we have expanded this trial internationally with the introduction of sites from Malaysia and the United Kingdom. We expect to engage 16 international sites to participate in the study with a target of 165 and 400 patients respectively over 3 years which will enable us to reach our recruitment target for this trial. In addition, the **HERO** Trial has also commenced recruitment and the next twelve months should see this trial meet its recruitment goals.

OUR GOVERNANCE STRUCTURE

The Operations Secretariat (OS) is the Brisbane-based hub of trial coordination and all AKTN activities. The Executive OS also includes collaboration with Vlado Perkovic and Alan Cass from the George Institute, Sydney. The OS reports on progress and activities to the DNT sub-committee of the Council of the Australian and New Zealand Society of Nephrology. The activities of the OS are also reported to the Advisory Board, which provides strategic guidance on the direction of the Network. All scientific activities of the OS are reported to and guided by the Scientific Committee, which provides expert advice and opinion on the scientific content of all trial proposals, in the context of the current approach of the Nephrological community.

Clinical trial proposals come to the AKTN via the OS, where they are passed through to the Scientific Committee for discussion. The management of all approved coordinated and facilitated trials is coordinated by OS staff, who also facilitate meetings by the clinical trial Data and Safety Monitoring Boards (DSMBs). The DSMBs are independent of the OS, the Scientific Committee, and the Advisory Board, in order to maintain objectivity.



STAFF PROFILES

Executive Operations Staff



Associate Professor Carmel Hawley

MBBS (Hons), M Med Sci, FRACP

Profile: Associate Professor Carmel Hawley is a Founding Member and current Chair of the Operations Secretariat for the Australasian Kidney Trials network (AKTN). She is a clinical nephrologist and biostatistician and is also involved in health services improvement in the areas of dialysis and chronic kidney disease. She has been a consultant nephrologist for 23 years and is a full-time employee of Queensland Health at Princess Alexandra Hospital, Brisbane, Queensland, in this capacity. Although trained in all aspects of nephrology, her early training was focused on renal hypertension. In latter years her primary interest has shifted to that of haemodialysis. She is currently the clinical manager of Haemodialysis at Princess Alexandra Hospital and was director of the Department from 1997 until 2002.

Associate Professor Hawley has had a 20 year involvement in clinical trials including international, national and locally conducted studies. This has included the management of the clinical trials portfolio of the PAH renal department for several years as well as the continuing supervision of research staff involved in trials on which she is a Principal or Associate Investigator. Dr. Hawley is regularly involved in teaching of epidemiology, biostatistics and clinical trial design at a national and state level.

Associate Professor Hawley has in the past, and continues to, contribute to relevant professional bodies. Past roles include that of Treasurer of the Australian and New Zealand Society of Nephrology (ANZSN), regional examiner for the Royal Australasian College of Physicians (RACP) Clinical Examination, member of the Dialysis Nephrology Transplant subcommittee of ANZSN, Board Member for Kidney Health Australia, involvement in two clinical guidelines groups associated with ANZSN (biochemical and haematological targets and bone disease) and Chair of the Specialist Advisory Committee (SAC) of the RACP (Nephrology). Current responsibilities include a membership of the CARI bone guideline group, Chair of the Home Dialysis Advisory Committee and Subject Editor for the *Journal Nephrology for Evidence Based Medicine*.



Professor David Johnson

MB BS (Hons) (Qld), PhD (Syd), FRACP

Profile: David Johnson is currently Director of Renal Medicine at Princess Alexandra Hospital, Brisbane, Australia, Professor of Medicine and Professor of Population Health at University of Queensland, Chair of the Queensland Statewide Renal Clinical Network, 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 and Deputy Chair of the Australasian Kidney Trials Network (based at Princess Alexandra Hospital), Founding Member of the NHMRC-endorsed Cardiovascular and Renal Centre of Clinical Research Excellence, Member of the ANZDATA Registry Peritoneal Dialysis 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, IDEAL, HERO, AVATAR, IMPENDIA and HONEYPOT trials. He has published over 400 original manuscripts in peer-reviewed journals and presented over 290 abstracts at national and international scientific meetings. He has won numerous research awards for his clinical and basic science studies in the areas of peritoneal dialysis outcomes, cardiovascular risk factor modification in uraemia, renal transplantation, dialysis unit infection control, treatment of acute renal failure and mechanisms of progressive chronic kidney disease. In 2005, he was awarded the TJ Neale Award by the Australian and New Zealand Society of Nephrology for “outstanding contributions to nephrologic science”. In 2011, he was awarded a Public Service Medal by the Governor-General of Australia for outstanding public service, particularly research into the early detection and management of kidney disease.



Professor Alan Cass

BA, MBBS, Grad Dip Clinical Epidemiology, FRACP, PhD

Profile: Professor Alan Cass is a Professor in the Sydney Medical School and Director of the Renal and Metabolic Division in The George Institute in Sydney. His research division at the George Institute undertakes collaborative, intervention research in Aboriginal health; works with governments to develop strategies to address the prevention and management of chronic vascular and metabolic diseases; and develops, undertakes, analyses and reports multi-centre clinical trials, individual patient meta-analysis and systematic reviews. He is particularly passionate about Aboriginal health, and his research collaborations with leading national and international Indigenous health researchers bring together quantitative and qualitative methods to develop, implement and evaluate interventions to improve chronic disease health outcomes for Indigenous Australians. Alan was recently appointed Co-Director of the Poce Centre for Indigenous Health at Sydney University.

Alan Cass trained as a renal physician at Royal Prince Alfred Hospital. He then completed a PhD at the Menzies School of Health Research in Darwin, in which he explored the social determinants of chronic kidney disease among Indigenous Australians. He received a Harkness Fellowship in health policy which influenced his subsequent international collaborative research aiming to improve health outcomes for disadvantaged populations facing an excess burden of complex chronic diseases.

Alan Cass is a member of the NSW Aboriginal and Population Health Priority Taskforce, a member of the NSW Coalition for Research to Improve Aboriginal Health (CRIA) Steering Group and is the Chair of the Australasian Kidney Trials Network's Scientific Committee. He is a leading proponent of academic collaboration in clinical research in kidney disease. He was the co-director of the Regional Coordinating study for the SHARP study, and is currently involved on the Trial Management Committees of the ACTIVE Dialysis, HERO, HONEYPOT, FAVOURED, BLOCADE and TransDiab trials.



Associate Professor Vlado Perkovic

MBBS PhD FRACP FASN

Profile: Associate Professor Vlado Perkovic is a clinician researcher with a substantial track record in nephrology research and clinical trials. He is Executive Director of George Clinical, the clinical trials implementation arm of the George Institute for Global Health and a part time staff-specialist in Nephrology at the Royal North Shore Hospital in Sydney. A/Prof Perkovic is involved in a number of local, regional and global organisations in kidney disease. He is Deputy Chair of the Australasian Kidney Trials Network's Scientific Committee, and is leading the development of a new international network of renal trialists. He Chairs the Cardiovascular guideline group for the Australasian renal guideline body (CARI- Caring for Australians with Renal Impairment), is a member of the dialysis adequacy guideline group, and is a member of the KDIGO (Kidney Disease-Improving Global Outcomes) group developing a global guideline for the management of blood pressure in people with kidney disease. He is a member of the Asia Pacific Forum for Chronic Kidney Disease Initiative renal registry group. He is also a member of the Kidney Check Australia Taskforce (KCAT) aiming to improve education about kidney disease in Australia.

A/Prof Perkovic is also Associate Professor at the University of Sydney. He has substantial expertise in the analysis of clinical trials as well as their conduct, having led key analyses of the recent ADVANCE trial, and participating in the recruitment of over 2400 participants from the Asia Pacific region to the SHARP trial. He chairs the Steering Committee for the ACTIVE Dialysis trial, and is a current member of several other Steering Committees including the CANVAS (4500 patients), PEXIVAS, HERO, IMPROVE, BLOCADE, AVATAR and FINESSE trials.

Since being awarded his PhD in 2005, A/Prof Perkovic has published over 60 peer-reviewed papers. He has been a chief investigator on 5 successful NHMRC project grants, and has previously been supported by NHMRC and Heart Foundation scholarships and post-doctoral fellowships, and was awarded the only 2010 NSW Office of Science and Medical Research Heart Foundation Career Development Fellowship.

Operations Staff



Dr Sunil Badve

Position: Research Fellow/Clinical Trialist

Centre: Australasian Kidney Trials Network

Qualifications: MBBS, MD, DNB, FRACP

Profile: Consultant nephrologist, Princess Alexandra Hospital; Clinical director, Peritoneal Dialysis Unit, Princess Alexandra Hospital; Senior Lecturer, School of Medicine, The University of Queensland; Clinical Trialist, AKTN

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Mrs Alicia Morrish

Position: Project Manager

Centre: Australasian Kidney Trials Network

Qualifications: BSc (Hons), MPH

Profile: Alicia has been working with the AKTN since April 2008. She has a Bachelor of Science (Hons) and Masters in Public Health, and prior to moving from Adelaide to Brisbane in 2006, had five years experience in bowel cancer screening trials. She also worked for the National Bowel Cancer Screening Program from 2006-2008. In 2010 she completed a Graduate Certificate in Clinical Trials Management through the University of Canberra. Her work at the AKTN includes assisting trial proposers in all aspects of trial development, up to the point of trial initiation, and securing new trials and funding for the network.

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Ms Peta-Anne Paul-Brent

Position: Project Officer

Centre: Australasian Kidney Trials Network

Qualifications: BSc Biotech, Grad Dip Biotech, CCRA

Profile: Peta has been working with the AKTN since June 2007 when she took on the role of the FAVOURED Project Officer. She has a Bachelor of Science in Biotechnology and Graduate Diploma also in Biotechnology. Her involvement in clinical trials started in 1998 when she started work for the Arthritis Research Group and then broadened with her move to the Australian Centre for Complementary Medicine Education and Research in 2001. In 2011, she successfully achieved Clinical Research Associate Certification; this is formal recognition of clinical research professionals who have met the eligibility requirements and demonstrated job-related knowledge and skills.

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Ms Donna Reidlinger

Position: Project Officer

Centre: Australasian Kidney Trials Network

Qualifications: BA, BAppS, MPH

Profile: Donna joined the AKTN in November 2008 and is currently the Project Officer for the HERO and PEXIVAS Trials. She graduated in 2010 from the University of Queensland with a Master of Public Health, and has since developed an interest in the growing burden of disease chronic illness places on our health and social systems. Donna has a particular interest in the food security and nutritional status of patients on dialysis, an area in which she hopes to one day complete a PhD.

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Dr Liza Vergara

Position: Project Officer

Centre: Australasian Kidney Trials Network

Qualifications: BS (Bio), MS (Bio), PhD (Science)

Profile: Liza Vergara joined the Australasian Kidney Trials Network in April 2009 and currently is the Project Officer for BLOCADE and HONEYPOT trials. Liza received her PhD in Science from QUT in 1999. Prior to her PhD studies, she has worked on population genetics research mainly on population bottlenecks, selection and conservation using fish as a model. After her postgraduate study, her family moved to Singapore in 2000 where she was involved in breast cancer research using microarrays and had worked as a Lab Manager in Genome Institute of Singapore from 2002-2005.

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Mr Charles Thompson

Position: Biostatistician

Centre: Australasian Kidney Trials Network

Qualifications: BA (Hons) MBiostat (UQ)

Profile: Charles completed a Master of Biostatistics through The University of Queensland, one of the eight universities within Biostatistics Collaboration Australia. He worked as an analyst in Queensland Health's Epidemiology Services Unit until 2006 when he joined the Australasian Kidney Trials Network. He is the statistician for a number of nephrology trials including HONEYPOT, HERO and FAVOURED.

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Ms Alaine Heffernan

Position: Coordinating Data Manager

Centre: Australasian Kidney Trials Network

Qualifications: BSc Human Nutrition & Dietetics - Trinity College Dublin

Profile: Elaine joined the AKTN in February 2010 as Coordinating Data Manager. She has a Bachelor of Science (Human Nutrition and Dietetics) and has six years experience working in clinical trials as a clinical research associate and clinical data programmer.

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Mrs Josephine Parry

Position: Executive Support Officer

Centre: Australasian Kidney Trials Network

Qualifications:
Dip. Frontline Management; Dip. Government (Investigations)

Profile: Josie joined the AKTN in April 2010 as the Executive Support Officer. Josie has many years experience working in key management and senior administrative roles within both the University and Public Sectors both in Queensland and the Northern Territory.

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TRIALS

The primary purpose of the Network is to cooperate with clinical investigators to develop research proposals into viable and successful clinical trials. The AKTN has established a robust process for the development of trial concepts into high quality clinical trials. We currently have trials that are either active or under development and are detailed in the following pages.

The AKTN has a process for endorsing, facilitating or coordinating trials.

Endorsed trials

A clinical trial that has the support of the AKTN and for which the AKTN assumes a limited number of duties, eg assistance with scientific content of protocol development, promotional activities, and occasionally formation of Data and Safety Monitoring Board (DSMB). Daily coordination of an Endorsed trial is not handled by the AKTN.

AKTN endorsed trials

ACTIVE Dialysis
L-Carnitine
FINESSE

Facilitated Trials

A trial for which the AKTN assumes responsibility for a limited number of coordination tasks on behalf of an International or other external Collaborative Research Group, eg local/regional site recruitment, coordination of regional sites, Sponsorship responsibilities (including Clinical Trials Agreements and indemnity as appropriate), and occasionally grant/budgetary responsibility. Usually a facilitated trial will not require AKTN involvement in protocol development, statistical analysis and the Data and Safety Monitoring Board (DSMB).

AKTN facilitated trials

PEXIVAS
AVATAR

Coordinated Trial

A trial that is being fully run by the AKTN, including assistance with scientific content, protocol, all ethical and regulatory documentation, Trial Management Committee, and formation of Data and Safety Monitoring Board (DSMB).

AKTN coordinated trials

FAVOURED
HONEYPOT
HERO
BLOCADE
IMPROVE
CKD-FIX
TransDiab

Active Trials



FAVOURED: Fish oil and Aspirin in Vascular access OUTcomes in RENal Disease (ACTRN12607000569404)

A randomised, double-blinded, placebo-controlled, factorial-design trial to assess the effect of aspirin and fish oil (omega-3 fatty acids) in the prevention of early thrombosis in arterio-venous fistulae in patients with Stage IV or V chronic kidney disease requiring haemodialysis.

Principal investigator: *Dr Ashley Irish Renal Unit, Royal Perth Hospital, Perth*

Trial Statistician: *Mr Charles Thompson, University of Queensland, Brisbane*

AKTN Project Officer: *Ms Peta-Anne Paul-Brent, University of Queensland, Brisbane*

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

Summary

FAVOURED is a multicentre, randomised controlled trial (RCT) with two-by-two factorial design. The objectives of this trial are to determine whether the use of the anti-platelet agents, aspirin or omega-3 fatty acids, will effectively improve postsurgical outcomes for patients with de novo arterio-venous fistulae (AVF).

The study population are patients with stage IV or V chronic kidney disease (CKD) who require or will require haemodialysis and who are scheduled to undergo creation of an AVF.

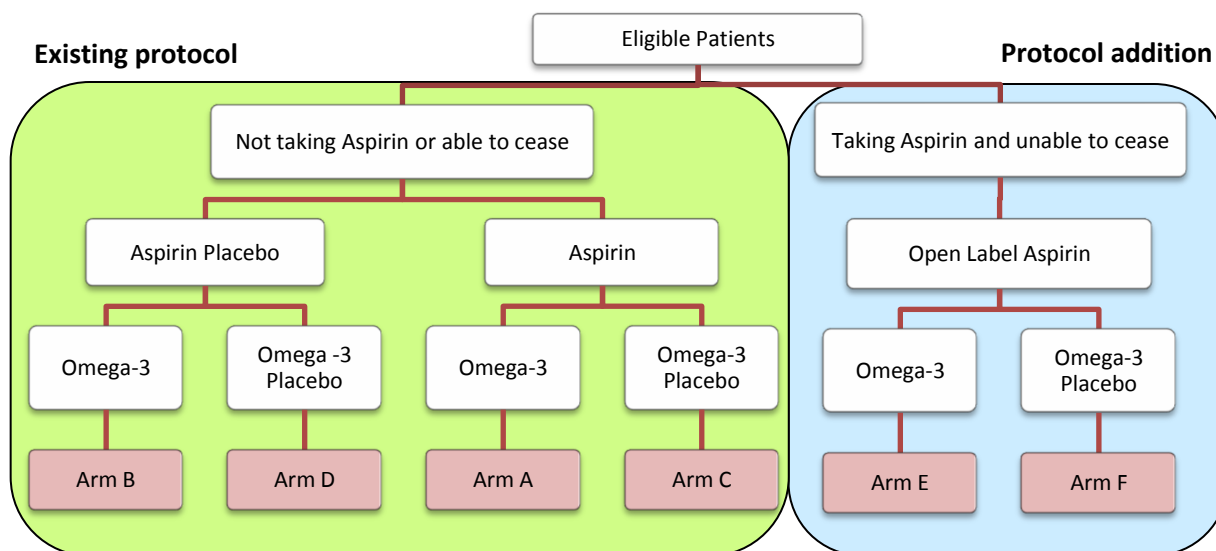
The primary objective of this trial is to determine whether the use of aspirin or fish oil is able to improve suitability failure of de-novo arterio-venous fistulae (AVF), compared to placebo within 12 months of surgery.

Progress update

We currently have 23 Australian sites and 2 New Zealand sites actively recruiting patients. We are in the final stages of initiating our new overseas sites with 9 sites in Malaysia and 8 sites in the United Kingdom with the aim to start recruitment in both countries in September 2010.

An ongoing concern for the Trial Management Committee is the lower than expected recruitment rate. To help speed recruitment and ensure that the participant recruitment target of 1200 is reached, the Trial Management Committee has made significant progress with the introduction of the overseas sites. However, in the current sites in Australia and New Zealand, the most significant reason for screening failure is the use of aspirin (39% of excluded patients required aspirin). The TMC is concerned that even with the addition of the UK and Malaysia, the recruitment rate may be affected by aspirin use and the study target may not be met in a timely fashion. In addition, a review of the baseline characteristic of patients has shown that the current study population was both young and healthy (average age = 55 years and with only 4% ischemic heart disease). This is not representative of the average stage 4/5 Chronic Kidney Disease cohort and has the potential of reducing the failure rate of studied AVFs and generalisability of the results to the wider renal population. With the dual purpose of improving the recruitment rate and bringing the study population characteristics in line with the general renal population, the TMC has decided to alter the protocol to allow patients taking aspirin to be randomised solely to fish oil or a matched placebo (see arms E and F in figure below). We believe this will allow us to better understand the potential added benefit of fish oil, on top of aspirin, in people at high cardiovascular risk, thus further illuminating the role of both agents in this large pool of patients.

The amended study protocol is as follows, and will be introduced in late 2010 / early 2011:





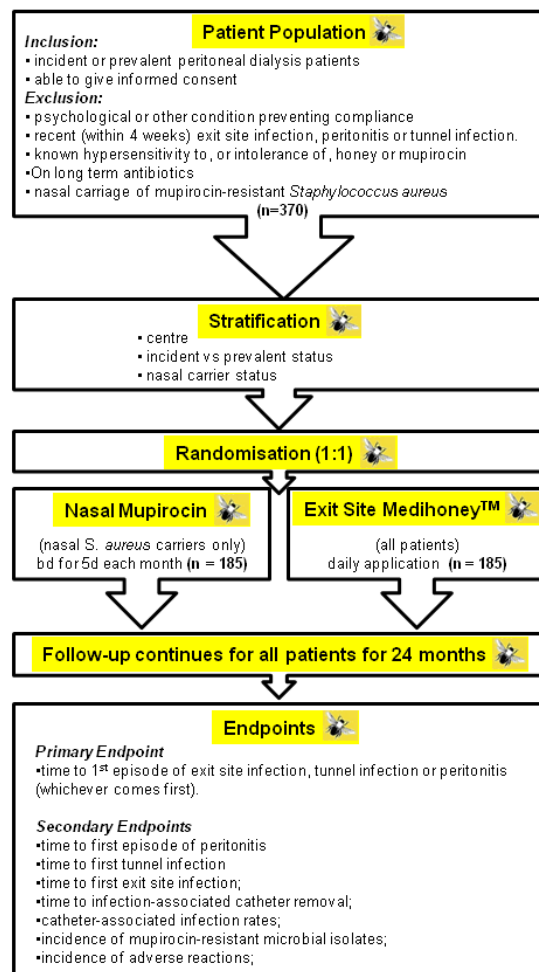
HONEYPOT: A randomised, controlled trial of exit site application of Medihoney™ Antibacterial Wound Gel for the prevention of catheter-associated infections in peritoneal dialysis patients (ACTRN12607000537459)

Principal investigator: Prof David Johnson, Department of Nephrology, Princess Alexandra Hospital, Brisbane

Trial Statistician: Mr Charles Thompson, University of Queensland, Brisbane

AKTN Project Officer: Dr Liza Vergara, University of Queensland, Brisbane

Trial Management Committee: David Johnson, Alan Cass, Charles Thompson, Janak de Zoysa, Carmel Hawley, Steven McTaggart, Geoffrey Playford, Alicia Morrish, Liza Vergara, Paul Snelling, Carolyn Clark



Summary

The main objective of the study is to determine whether daily exit site application of standardised antibacterial honey (Medihoney™ Antibacterial Wound Gel), in addition to daily cleansing as per standard practice, effectively prevents exit site infections, tunnel infections and peritonitis in peritoneal dialysis (PD) patients compared with standard topical mupirocin prophylaxis of nasal staphylococcal carriers (currently recommended by the CARI clinical practice guidelines).

The study includes both incident and prevalent peritoneal dialysis patients who are able to give informed consent. Patients will be excluded if they have had: 1) A history of psychological illness or condition which interferes with their ability to understand or comply with the requirements of the study; 2) Recent (within 1 month) exit site infection, peritonitis, or tunnel infection; and 3) Known hypersensitivity to or intolerance of honey or mupirocin. 370 subjects will be randomised 1:1 to receive either daily, topical exit site application of Medihoney™ Antibacterial Wound Gel (Medihoney Pty Ltd, Australia) (all patients) or nasal application of mupirocin (nasal carriers only). All patients in the control and intervention groups will perform usual exit site care according to local practice.

Progress update

The HONEYPOT Trial is proceeding very well with all 26 active sites successfully recruiting patients. A total of 281 participants have been recruited to date out of the target of 370 participants. The countdown to reach recruitment of the final patient has started and all sites are being encouraged to keep on recruiting until the target of 370 patients is reached.

The Data and Safety Monitoring Board of HONEYPOT are due to review progress of the trial at a meeting scheduled for October 2010. All sites have received at least one on-site monitoring visit to date.



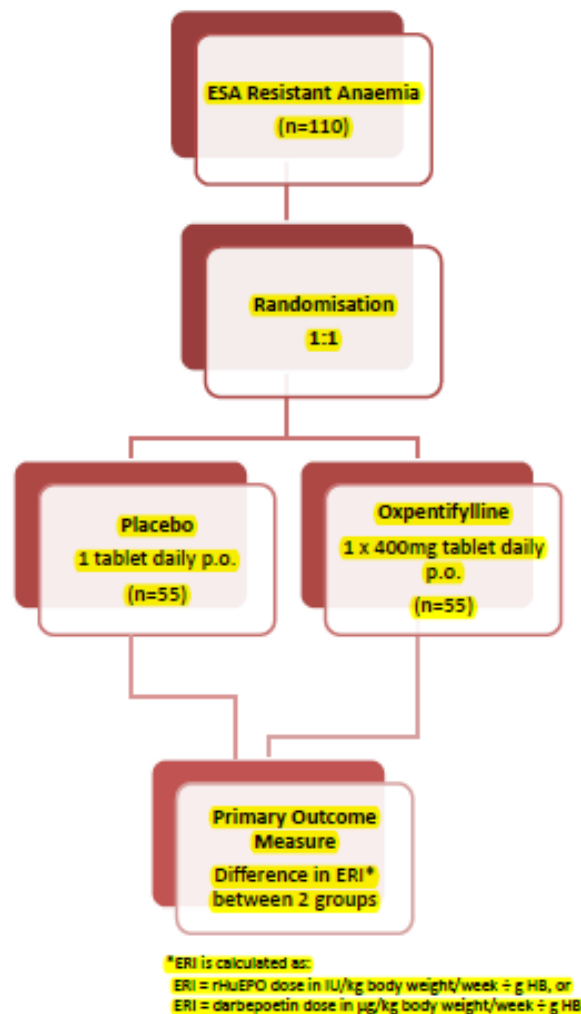
HERO: Haemoglobin levels in patients with Erythropoietin-Resistant anaemia treated with Oxpentifylline (ACTRN12608000199314)

Principal investigator: Prof David Johnson, Department of Nephrology, Princess Alexandra Hospital, Brisbane

Trial Statistician: Mr Charles Thompson, University of Queensland, Brisbane

AKTN Project Officer: Ms Donna Reidlinger, University of Queensland, Brisbane

Trial Management Committee: David Johnson, Charles Thompson, Rob Fassett, Carmel Hawley, Alan Cass, Stephen McDonald, Alicia Morrish, Rowan Walker, Genie Pegadogos, Donna Reidlinger, Vlado Perkovic, Carl Kirkpatrick



Summary

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 (Hb 120 g/L) that is unresponsive to large doses of either erythropoietin (EPO) or darbepoietin (DPO) and therefore have a high Erythropoietin Resistance Index (ERI), and for which there is no clear identifiable cause. Patient's EPO/DPO dosage should be unchanged in the 8 weeks leading up to Randomisation.

Exclusion criteria include patients with a history of psychological illness or condition which interferes with their ability to understand or comply with the requirements of the study; pregnancy or breast-feeding; known hypersensitivity to, or intolerance of, oxpentifylline or other methylxanthines; history of **major** gastrointestinal bleeding or **any** gastrointestinal bleeding in the past 12 weeks; absolute or functional iron deficiency; vitamin B12 or folate deficiency; parathyroid hormone level > 100 pmol/L; serum aluminium > 2 µmol/L; urea reduction ratio < 65% or single pool Kt/V < 1.0 (haemodialysis patients) or total weekly Kt/V < 1.7 (peritoneal dialysis patients); presence of systemic haematological disease or known haemoglobinopathy; active haemolysis; major surgery, infection, acute myocardial infarction or malignancy within the last 12 weeks; melatonin treatment, androgen therapy or blood transfusion within the previous 4 weeks; vitamin C therapy at a dose greater than 1000 mg/day or at a dose which has changed within the last 12 weeks; haemorrhagic stroke or severe haemorrhage within the last 12 weeks, and immunosuppression during the past 4 weeks.

The study is a prospective, double-blind, randomised, placebo-controlled phase 3 trial. Patients are randomised 1:1 to receive either placebo (1 tablet daily) or oxpentifylline (1x400mg tablet daily) per os for a period of 4 months. During this 4 month study period, haemoglobin measurements will be performed monthly. The primary outcome measure will be the difference in Erythropoietin Resistance Index between the 2 groups at the end of the 4 month study period, adjusted for baseline values. Secondary outcome measures will include change in Hb concentration, reduction in ESA dosage, and blood transfusion requirement.

Progress update

The Trial currently has 13 Australian sites actively recruiting patients and a further site beginning ethics and governance approvals. To date there have been 13 patients randomised from a target of 110.

In response to publications from other clinical research trials (TREAT, CHOIR), the Trial Management Committee voted to change the inclusion criteria and primary outcome measure. This change was due to reported associations between high Hb targets and thromboembolic events in CKD patients. In March 2010, the inclusion criteria were changed from a focus on ESA dose and haemoglobin targets to an ERI ≥ 2.0 IU/kg/week/gHb for erythropoietin treated patients and ≥ 0.01 µg/kg/week/gHb for darbepoietin treated patients, and the primary outcome measure to a difference in ERI between the 2 groups at the end of the treatment period. A review of the Renal Anaemia Management (RAM) database from South Australia suggested that approximately 20-25% of all patients receiving haemodialysis would be eligible to participate in the HERO trial according to the the ERI-based inclusion criteria.



ACTIVE Dialysis

Principal investigator: *Dr Vlado Perkovic, The George Institute for Global Health, Sydney NSW*

Trial Statistician: *Mr Charles Thompson, University of Queensland, Brisbane, QLD*

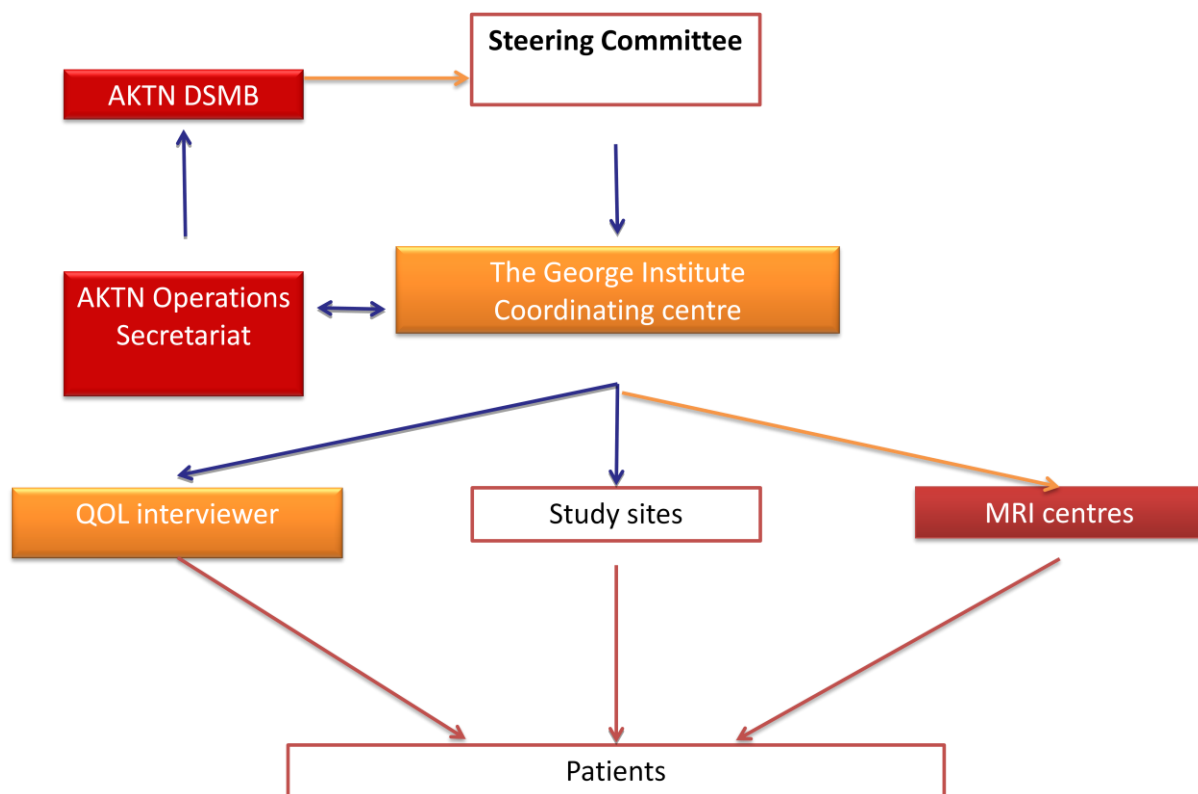
AKTN Project Officer: *Insert here, University of Queensland, Brisbane, QLD*

Trial Management Committee: Chair: *A/Prof Vlado Perkovic, Executive Director, The George Institute for International Health, Prof Alan Cass, Dr Meg Jardine, Dr Martin Gallagher, Dr Eleanora Fjälling.*

Optional Observers: *As determined from time to time by the Management Committee, eg, The Study Monitor.*

Summary

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. Led by a steering committee of nephrologists and endorsed by the AKTN, the study is coordinated by the Renal Division at The George Institute for International Health. The trial is funded by a National Health and Medical Research Council (NHMRC) Project Grant with a supplementary unrestricted grant from Baxter. Participants are being enrolled from both the home haemodialysis and in-centre settings and are randomized to standard or extended weekly hours of haemodialysis for 12 months.



Progress update

ACTIVE now has 53 participants enrolled. There are currently 16 sites in Australia and New Zealand, 3 sites in Canada with another nearing completion of Ethics and regulatory processes. In the UK 3-4 sites are awaiting regulatory approval. The study now has more participants than the only published trial of extended hours dialysis. ACTIVE appears likely to provide landmark evidence on the question of the benefits and harms of extended hours dialysis.

Any interested sites are still able to join the study and are invited to contact Meg Jardine (mjardine@georgeinstitute.org.au) or Vlado Perkovic (vperkovic@georgeinstitute.org.au) for further information.

Trials under Development



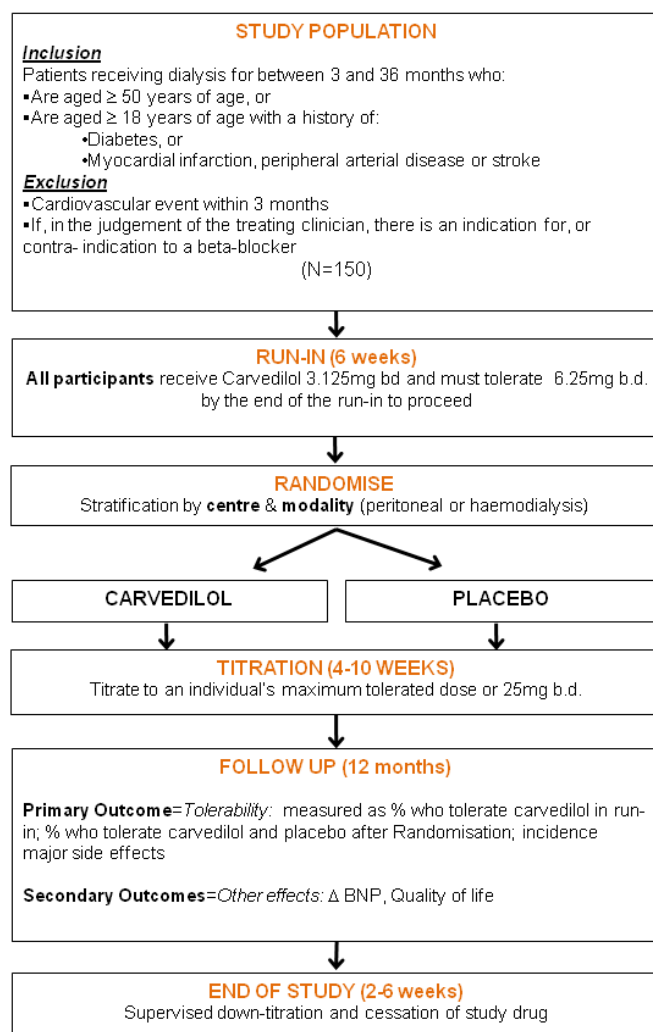
BLOCADE: Beta-blocker to Lower Cardiovascular Dialysis Events (ACTRN 12609000174280)

Principal investigator: Dr Matthew Roberts, Department of Nephrology, Austin Health

Trial Statistician: Mr Charles Thompson, University of Queensland, Brisbane

AKTN Project Officer: Dr Liza Vergara, University of Queensland, Brisbane

Trial Management Committee: Matthew Roberts, Frank Ierino, Henry Krum, Carmel Hawley, Alan Cass, Nicole Isbel, Helen Pilmore, Andrew Tonkin, Vlado Perkovic, Amit Garg



Summary

This trial aims to investigate whether the beta-blocker carvedilol is effective in reducing the incidence of cardiovascular morbidity and mortality in patients receiving dialysis. In the first instance the AKTN are performing a Feasibility study. The major outcomes of this Feasibility study will be to assess tolerability of carvedilol, recruitment rates, and event rates which will provide baseline data for a larger clinical endpoint study planned in the future. The trial will recruit 150 participants and will follow them for 12 months with a supervised down-titration and cessation of study drug at the end of the study. Funding for this study has been obtained from 4 grants - Jacquot grant application (\$AU700K over 3 years), Pfizer CVL (\$AU55K), Health Research Council of New Zealand (\$NZ156K for NZ sites only) and NHMRC (\$AU580K over 3 years).

Progress update

To date, 10 sites (Australia = 7 sites, New Zealand = 3 sites) have confirmed their participation in the study and are in various stages with ethics approval and documentation. Procurement of study medication has been completed and manufacture of placebo is currently underway. Medication will be available to sites by March 2011. Initiation meetings are to be conducted in February 2011 in Auckland for New Zealand sites, and in Melbourne, for Australian sites, which will provide an opportunity for Investigators and site coordinators to feedback on the trial logistics and changes to Case Report Forms (CRFs). Recruitment is expected to begin in April 2011 for all sites that are ready. The Endpoint Adjudication Committee and Data and Safety Monitoring Board are organised and the first meetings are planned for April 2011.



The
PEXIVAS
trial

PEXIVAS:

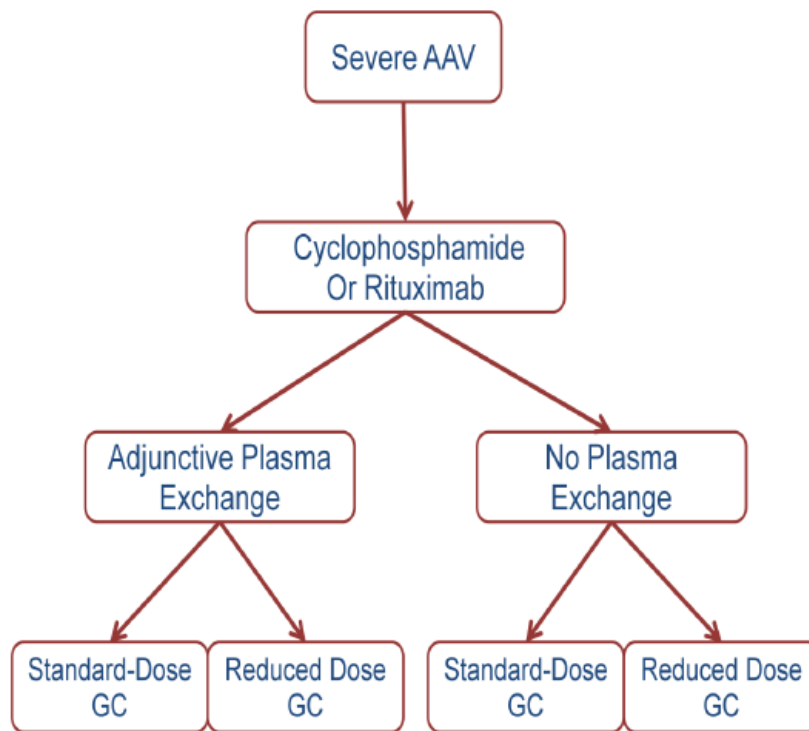
Principal investigator: Dr Chen Au Peh, University of Adelaide

Chief Investigators: Peh CA, Jayne D, Merkel P, Walsh M, Perkovic V, Kerr P

Trial Statistician: Mr Charles Thompson, University of Queensland, Brisbane

AKTN Project Officer: Ms Donna Reidlinger, University of Queensland, Brisbane

Trial Management Committee: Chen Au Peh, Randall Faull, Janak de Zoysa, Peter Kerr, Robyn Langham, Giles Walters, Vlado Perkovic, Sunil Badve



Summary

ANCA-associated vasculitis is a life-threatening disease. The PEXIVAS project will investigate whether plasma exchange, in addition to immunosuppressive therapy and glucocorticoids, will reduce death and the development of severe kidney failure due to this disease. Additionally, the project will also look at whether using a reduced dose of glucocorticoids is just as effective as larger doses in lessening the infectious complications of treatment.

Eligible patients will be randomized to receive either:

1. Plasma exchange in addition to standard of care immunosuppressive therapy and glucocorticoids or,
2. Standard of care immunosuppressive therapy and glucocorticoids without plasma exchange.

In addition, all patients will also be randomized to receive either a reduced-dose glucocorticoid treatment or a standard-dose glucocorticoid treatment in a 2-by-2 factorial clinical trial design format.

The trial is an international collaboration which has to-date recruited 19 patients in the United Kingdom and Europe. Before patients can start enrolling into this trial in Australia and New Zealand, many contractual negotiations have to be finalised. These contracts include an overarching agreement between Royal Adelaide Hospital (the grant holder) and the Australasian Kidney Trials Network (AKTN), the co-ordinating centre for the region; an additional contract between the Cambridge NHS Trust and Royal Adelaide Hospital; individual contracts between the 22 participating Australian renal units and the AKTN; and individual contracts between the 5 New Zealand sites and the AKTN. Further, ethical and regulatory approvals have to be obtained. The investigators are glad to report that most of these contractual, ethical and regulatory processes are in their final phases of completion.

Additionally, the AKTN has negotiated with industry partners, Gambro and Fresenius, the reimbursement to sites of the consumables used during the plasma exchange procedure. These companies have agreed to support the study by crediting sites for filters, anti-contamination chambers and lines used to treat PEXIVAS trial participants who are randomised to the plasma exchange arm of the trial.

Progress update

It is anticipated that during the five year recruitment period Australian and New Zealand sites will be able to consent approximately 100 patients to the trial. A number of sites have already completed the time-consuming task of obtaining ethics and governance approval and will be ready to begin recruitment as soon as all outstanding legal issues have been finalised.

PEXIVAS is currently on track to start patient enrolment in April 2011.



AVATAR: ACE Inhibition for the Preservation of Renal Function and Patient Survival in Kidney Transplantation

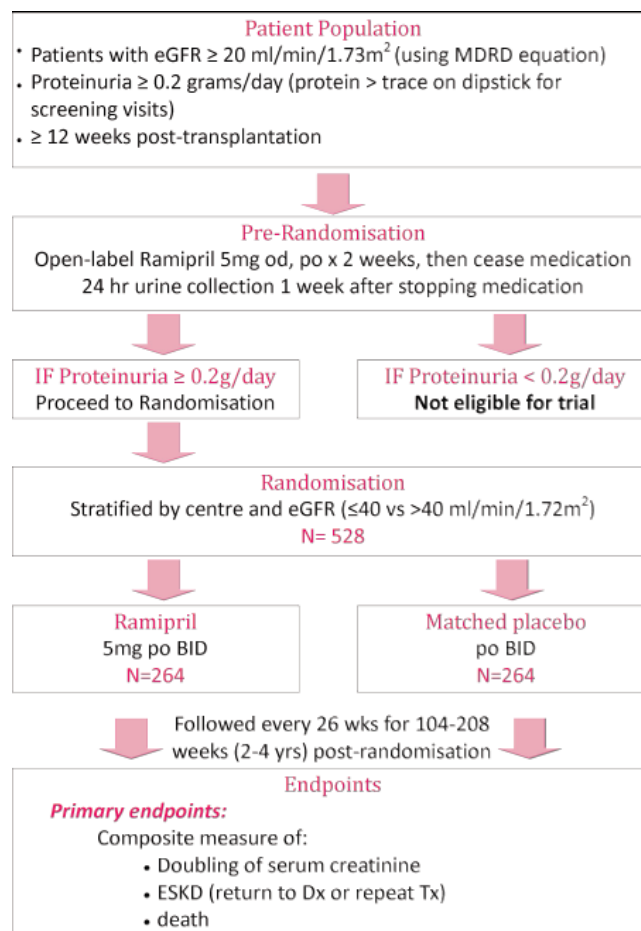
(Local acronym: AVATAR - Ace inhibitors Versus pLAcebo Therapy After Renal transplantation)

Principal investigator: Dr Greg Knoll, Ottawa Hospital Research Institute, Ottawa, Canada
Local (ANZ Principal Investigator: Dr Helen Pilmore, Auckland City Hospital, New Zealand)

Trial Statistician: Mr Charles Thompson, University of Queensland, Brisbane

AKTN Project Officer: TBA (contact AKTN Project Manager Alicia Morrish for trial details)

Trial Management Committee: Helen Pilmore (Chair), Nikky Isbel, Jeremy Chapman, Josette Eris, Neil Boudville, Graeme Russ, Matthew Jose, Rowan Walker, John Kanellis, David Johnson, Vlado Perkovic, Sunil Badve, Alicia Morrish



Progress update

Negotiations are currently underway to facilitate the Australian and New Zealand arm of an international study investigating Ace Inhibitor use in Kidney transplantation. This trial is being led internationally by Dr Greg Knoll and the Ottawa Hospital Research Institute. Dr. Helen Pilmore will chair the trial management committee for the Australian and New Zealand investigators in this trial. Funding will be provided by the Canadian Institute of Health Research. The first ANZ Trial Management Committee teleconference is expected to be held in August 2010, and local recruitment is expected to commence in late 2011.



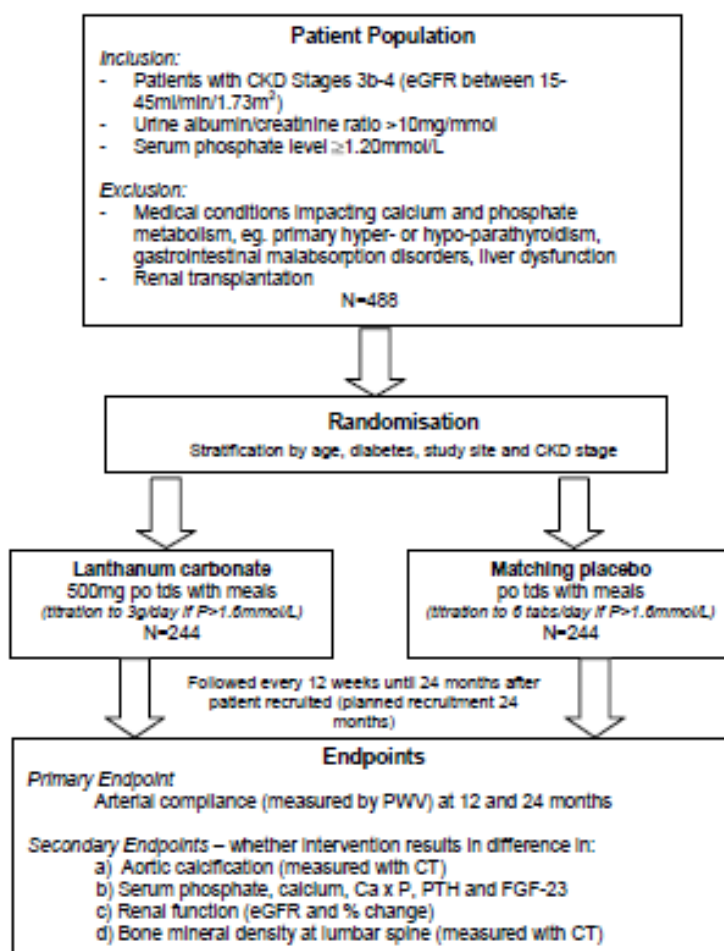
IMPROVE: Impact of Phosphate Reduction On Vascular End-points in Chronic Kidney Disease

Principal investigator: Dr Nigel Toussant, Department of Nephrology, Monash Medical Centre, Melbourne, Victoria and Dr Genie Pedagogos, Department of Nephrology, Royal Melbourne Hospital, Melbourne, Victoria.

Trial Statistician: Mr Charles Thompson, University of Queensland, Brisbane

AKTN Project Officer: TBA (contact AKTN Project Manager Alicia Morrish for trial details)

Trial Management Committee: Eugenie Pedagogos (Co-Chair), Nigel Toussaint (Co-Chair), Randall Faull, Grahame Elder, Carol Pollock, Ken Lau, Kevan Polkinghorne, Neil Boudville, Peter Kerr, Rob Walker



Progress update

Arrangements are being finalised to coordinate a multi-centre Australian and New Zealand trial investigating phosphate reduction through Lanthanum use, and its effect on arterial compliance and vascular calcification in Chronic Kidney Disease (CKD) patients. This trial is being led by Dr. Nigel Toussaint and Dr. Eugenie Pedagogos (Melbourne), and funding has been made available via an unrestricted grant from Shire Pharmaceuticals.

This trial will be conducted in collaboration with Dr David Wheeler in the United Kingdom, where additional sites will participate in patient recruitment. The first Trial Management Committee teleconference is to be conducted in July 2010, and recruitment commencement at the 17 confirmed Australian and New Zealand sites is likely to occur in June 2011, with potentially 6 UK sites to become active soon after. This will be the first study involving a true partnership of ANZ and UK investigators. Such international collaboration is important to achieve our goal of performing studies with adequate power to address clinically relevant questions

Trial funding of \$1.5m from Shire has been received. A request for \$300,000 for ancillary studies on the mechanistic pathways of lanthanum carbonate is to be submitted to the NHMRC in early 2011.



TransDiab:

Principal investigator: *Dr Helen Pilmore*

Trial Statistician: *Mr Charles Thompson, University of Queensland, Brisbane*

AKTN Project Officer: *TBA (contact AKTN Project Manager Alicia Morrish for trial details)*

Trial Management Committee: *Dr Helen Pilmore (Chair), Professor Alan Cass, Associate Professor Carmel Hawley, Dr Sophie Zoungas, Dr Josette Eris, Associate Professor John Kanellis, Dr Kate Wyburn, Dr Scott Campbell.*

Summary

The goal of the TRANSDIAB trial is to explore the efficacy, safety and tolerability of metformin in the management of disorders of glucose metabolism following kidney transplantation. This study was proposed and developed by leading Australian and New Zealand renal transplant physicians with support of the AKTN. This study will provide essential data on incidence of prediabetes and NODAT in kidney transplant recipients; feasibility of recruitment; safety, tolerability and glucose lowering efficacy of metformin in this patient population.

Progress update

A Trial Protocol has now been developed, and an application for funding is to be submitted to the NHMRC in March 2011.



CKD-FIX:

Principal investigator: Prof David Johnson, Department of Nephrology, Princess Alexandra Hospital, Brisbane

Trial Statistician: Mr Charles Thompson, University of Queensland, Brisbane

AKTN Project Officer: TBA (contact AKTN Project Manager Alicia Morrish for trial details)

Trial Management Committee (proposed): David Johnson, Fiona Brown, Vlado Perkovic, Carmel Hawley, John Kanellis, Gopala Rangan, Rob Fassett, Sunil Badve, Giles Walters, Janak de Zoysa, WA (TBC), SA (TBC)

Summary

The Primary aim of this trial is to test the hypothesis that uric acid lowering therapy with allopurinol results in slowing the progression of chronic kidney disease (CKD) as determined by change in glomerular filtration rate (GFR).

The Secondary aim of this trial is to assess the effect of allopurinol on -

- (a) serum uric acid concentration
- (b) blood pressure
- (c) albuminuria
- (d) 50% or ≥ 25 ml/min/1.73 m² reduction in GFR
- (e) progression to ESRD requiring dialysis or kidney transplantation
- (f) death
- (g) cardiovascular events
- (h) adverse events

The effect of allopurinol on the following measures will be studied in ancillary studies -

- (a) inflammatory markers (IL-6, CRP)
- (b) left ventricular mass index
- (c) pulse wave velocity.

Progress update

The recruitment target for this trial is 640 participants. A Project Grant application will be submitted to the NHMRC in March 2011.

FUNDING

Summary

This year has proven successful with the extension of the NHMRC Enabling Grant (\$2 million over the next 5 years) which will provide much needed infrastructural support. In addition, the BLOCADE trial has recently received an additional NZ\$156,000 from Health Research Council of NZ to be used for our New Zealand sites.

Funding breakdown



AKTN Infrastructure funding

National Health and Medical Research Council (NHMRC) Enabling Grant
Enabling Grant: ID 338800
Funding period: 2006-2010
\$1,290,000

National Health and Medical Research Council (NHMRC) Enabling Grant
Enabling Grant: ID 631731
Funding period: 2010-2015
\$2,000,000



National Health and Medical Research Council (NHMRC) Project grant – via University of WA
Project grant no: ID 458 652
Funding period: 2007-2010
\$1.79 million



Baxter Clinical Extramural Grant
Funding period: 2008-2010
\$375,000 US

QLD Health, Smart Health Award
Funding period: 2008-2011
\$432,000

Gambro unrestricted grant
Funding period: 2008
\$5,000



Roche Foundation for Anaemia Research (RoFar) Grant
Funding period: 2007-2009 (extended to 2011)
\$192,820

Amgen unrestricted Grant
Funding period: 2008-2010
\$110,000

Janssen Cilag unrestricted Grant
Funding period: 2007-2008
\$10,000

NHMRC Project Grant
Grant no: APP1008604
Funding period: 2011-2013
\$333,408



Don & Lorraine Jacquot Collaborative Research Initiative Grant
Funding period: 2008-2010 (extended to 2011)
\$700,000 over 3 years

Pfizer CVL grant
Funding period: 2009
\$55,000

Health Research Council of New Zealand – via Auckland City Hospital
Funding period: 2010-2013
NZ\$156,000 (for NZ use only)

National Health and Medical Research Council (NHMRC) Project grant – via University of Melbourne
Project Grant no: ID APP1006171
Funding period: 2011 - 2013
\$579,527.20



National Health and Medical Research Council (NHMRC) Project grant – via University of Adelaide
Project Grant no: ID APP 626939
Funding period: 2010 - 2014
\$604,375



The main clinical component of trial is funded by an unrestricted grant from Shire.
Funding period: 2010-2014
\$1,503,578

Despite our recent success, we are continually seeking additional funding for our current trials. If you are interested in becoming financially involved with the AKTN, please contact us directly for further information (aktn@uq.edu.au)

FINANCE

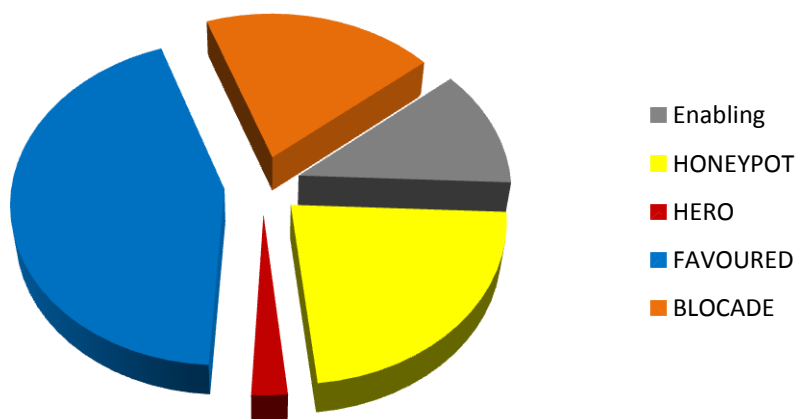
At the end of the financial year 30 June 2010, the AKTN surplus was \$1,106,095, which is accounted for in budget projections.

AKTN EXPENDITURE 1 JULY 2009 – 30 JUNE 2010

Trial	Expenditure	Accumulated position at 30 June 2010
Enabling	\$134,926	-\$123,884
HONEYPOT	\$259,256	\$255,962
HERO	\$28,535	\$89,238
FAVOURED	\$500,215	\$940,316
BLOCADE	\$221,005	-\$55,537
TOTAL	\$1,143,947	\$1,106,095

The negative accumulated position for the enabling account is to be rectified at the next income instalment (October 2010). The negative accumulated position for the BLOCADE account reflects the arrangement with University of Melbourne where expenditure is reimbursed by the NHMRC grant retrospectively. The true accumulated position of this grant at end June 2010 is \$520,995 (funds held by University of Melbourne).

AKTN Operating Expense Summary 1 July 2009 - 30 June 2010



The larger expenditure of the FAVOURED trial reflects the large scale of the trial (1200 participants; 4 countries).

Although coordination of the PEXIVAS & IMPROVE trials (planning stages) commenced in early 2010, at the time of this report (30 June 2010), no income had yet been transferred, so these trial budgets are not represented in this summary.

PHD OPPORTUNITIES

The AKTN is committed to provide support for Ph. D. candidates. There are opportunities to conduct research in the various aspects of clinical trials:

- developing new trials;
- trial methodology; and
- analysis of data.

Currently, the AKTN is supporting further education in the field of Nephrological research by contributing to the PhD. scholarship stipend of Min Jun (supervised by Professor Alan Cass and Associate Professor Vlado Perkovic).

Interested candidates are advised to contact Associate Professor Carmel Hawley or any member of the Operations Secretariat or Scientific Committee.

NETWORK STAFF AND COMMITTEES

Current 30 June 2010

ADVISORY BOARD

Prof David Harris (Chair), University of Sydney
A/Prof Mark Bowles, Mater Medical Research Institute, Brisbane
Prof Phil Aylward, Department of Cardiovascular Medicine, Flinders Medical Centre
A/Prof Val GebSKI, NHMRC Clinical Trials Centre, Sydney
Mr David Cairns, Macquarie University, Sydney (retired December 2009)
Ms Angela Reddy, Kidney Health Australia

SCIENTIFIC COMMITTEE

Prof Alan Cass (Chair), George Institute for International Health, Sydney
A/Prof Vlado Perkovic (Deputy Chair), George Institute for International Health, Sydney
Dr Phillip Clarke, University of Sydney
Dr Bruce Cooper, Royal North Shore Hospital, Sydney
Prof Jonathan Craig, Westmead Children's Hospital, Sydney
Ms Maria Farrell, Research Nurse Coordinator, Royal Melbourne Hospital
Prof Peter Kerr, Monash Medical Centre, Melbourne
Dr Steven McTaggart, Royal Children's Hospital, Brisbane
A/Prof Stephen McDonald, Queen Elizabeth Hospital, Adelaide
Dr Helen Pilmore, Auckland City Hospital, New Zealand
Dr Kevan Polkinghorne, Monash Medical Centre, Melbourne
Dr. Paul Snelling, Royal Prince Alfred Hospital, Sydney
Prof Rowan Walker, Royal Melbourne Hospital

OPERATIONS SECRETARIAT

A/Prof Carmel Hawley (Chair), Princess Alexandra Hospital
Prof David Johnson (Deputy Chair), Princess Alexandra Hospital
Dr Melissa Bruce, Business Development Manager
Dr Sunil Badve, Clinical Trialist
Mrs Alicia Morrish, Project Manager
Mr Charles Thompson, Statistician
Ms Elaine Heffernan, Coordinating Data Manager
Ms Peta-Anne Paul-Brent, Project Officer
Dr Liza Vergara, Project Officer
Ms Donna Reidlinger, Project Officer
Mrs Josephine Parry, Executive Support Officer



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