

AUSTRALASIAN KIDNEY TRIALS NETWORK

THE GOVERNANCE AND POLICIES OF THE AUSTRALASIAN KIDNEY TRIALS NETWORK

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AUSTRALASIAN KIDNEY TRIALS NETWORK

Introduction

- The need for a clinical trials network in the area of kidney disease was recognized by both the Australian and New Zealand Society of Nephrology (ANZSN) Council and Kidney Health Australia (KHA).
- In October 2003, ANZSN and KHA asked for expressions of interest to run such a network.
 - Three groups were chosen to submit full proposals
 - In August 2004 the proposal for the network with a Brisbane-based Operations Secretariat was endorsed by both ANZSN and KHA.

AUSTRALASIAN KIDNEY TRIALS NETWORK

Introduction

- The Australasian Kidney Trials Network (AKTN) was established with initial funding from both KHA (\$50,000 per year for three years) and ANZSN (\$30,000 per year for three years).
- In 2005, the AKTN was successful in obtaining a National Health and Medical Research Council (NHMRC) enabling grant to assist with infrastructure support.
- Since 2005, the Network has been successful in leveraging more than \$3.5 million in other funding for individual trial projects.

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Aims of the Network

- The AKTN was established to improve the capacity to conduct and support high quality investigator initiated clinical trials in kidney disease, focused on appropriate patient-centred outcomes
- The AKTN facilitates well-conducted clinical research and fosters collaborations between leading researchers in kidney disease.

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AKTN Governance

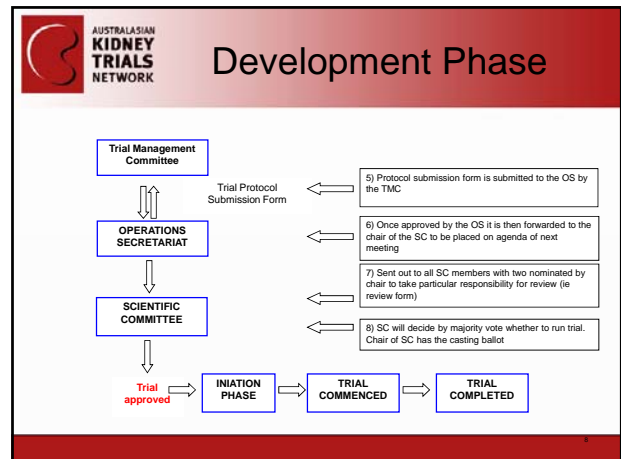
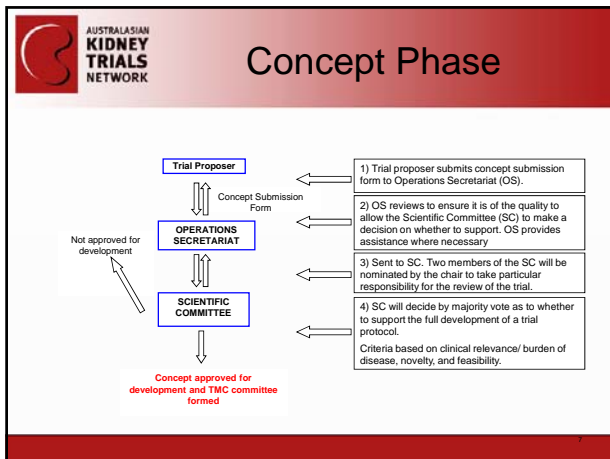
- The AKTN is managed by three different groups in Australia & New Zealand to ensure a sound governance structure
 - The Advisory Board
 - The Scientific Committee
 - The Operations Secretariat

AUSTRALASIAN KIDNEY TRIALS NETWORK

AKTN Governance

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graph TD
    AB[Advisory Board] --> SC[Scientific Committee]
    AB --> OS[Operations Secretariat]
    SC <--> OS
    SC --> RP[Research Proposals]
    RP --> CT1[Clinical trial 1]
    RP --> CT2[Clinical trial 2]
    RP --> CT3[Clinical trial 3]
    OS --> CT1
    OS --> CT2
    OS --> CT3
    CT1 --> SDMC[Safety and Data Monitoring Committee]
    CT2 --> SDMC
    CT3 --> SDMC
  
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- ## AKTN Policies and Procedures
- In addition to the sound governance, the AKTN has developed a set of policies and procedures to oversee the regulation of all clinical trials either coordinated or endorsed by the AKTN.
 - Coordinated trials utilise the AKTN resources to develop and run the trial and data is managed or coordinated centrally and will have the full resources of the network available to develop the protocol and run the trial.
 - In endorsed trials, the network will offer assistance in some aspects of the trial design but will not run the trial or manage the data.

- ## AKTN Policies and Procedures
- All policies and procedures are developed by the Operations Secretariat upon advice from the Advisory Board.
 - Policies and procedures are approved by the Scientific Committee before being given final approval by the Advisory Board.
 - All AKTN official policies are available on our website at:

<http://www.aktng.org.au/index.html?page=27243&pid=26713>



- ## Current AKTN Policies and Procedures
- Current Policies include:
 - Publication Policy 1.1 (AKTNPOL 1)
 - Duality of Interest Policy 1.1 (AKTNPOL 2)
 - Dispute Resolution Policy 1.1 (AKTNPOL 3)
 - Ethics Policy 1.1 (AKTNPOL 4)
 - Inclusion of chief investigators (AKTNPOL 5)
 - Reporting Relations (AKTNPOL 7)
 - Reimbursement (AKTNPOL 8)
 - Endorsement policy (AKTNPOL 9) (Draft)
 - Risk Management policy (AKTNPOL 10) (Draft)
 - Organisation and Procedures (AKTNSOP 1)

- ## Summary
- A total of 15 concepts have been proposed to the network since its inception in 2005
 - Of these 15 proposals, 3 have now been developed into full protocols for which recruitment is now commencing for HONEYPOT and FAVOURED with HERO expected to be launched in October 2008.
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A randomised, controlled trial of exit site application of Medihoney™ Antibacterial Wound Gel for the prevention of catheter-associated infections in peritoneal dialysis patients

Principal Investigator: Prof David Johnson (Qld)
Study Coordinator: Alicia Smith
a.smith18@uq.edu.au


A randomised, double-blind, placebo-controlled, factorial-design trial to assess the effect of aspirin and fish oil in the prevention of early thrombosis in arterio-venous fistulae in patients with Stage IV or V CKD requiring haemodialysis

Principal Investigator: Dr Ashley Irish (WA)
Study Coordinator: Peta-Anne Paul Brent
p.kerr@uq.edu.au



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

Principal Investigator: Prof David Johnson (QLD)
Study Coordinator: Alicia Smith
a.smith18@uq.edu.au



Summary

- In addition to our three active trials, 2 trial proposals are in the early stages of development

- Each will involve extensive collaboration with study sites in Australia and New Zealand.



Conclusion

- This process of trial development has been successful in developing high quality, clinically important, and feasible investigator initiated clinical research in kidney disease in Australia and New Zealand.



Contact us

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AUSTRALASIAN KIDNEY TRIALS NETWORK

Rationale

- Peritoneal Dialysis (PD) is a widely used therapy in Australasia
- The main limitation of this therapy is the occurrence of infectious complications
 - Exit site infection is the most common infectious complication and is associated with a substantially increased risk of peritonitis & catheter removal

The optimal means of providing exit site care with the goal of preventing exit site infections is unknown

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Primary Objective

To determine whether daily exit site application of standardised antibacterial honey, in addition to daily cleansing, more effectively prevents exit site infections, tunnel infections and peritonitis in PD patients compared with standard topical mupirocin prophylaxis of nasal *staphylococcal* carriers

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Study Treatments

- Both arms:**
Usual local exit site cleaning procedure PLUS
- Control arm:**
Intranasal mupirocin for 5 days each month for *staph* nasal carriers only
- Intervention:**
Daily exit site application of Medihoney™ antibacterial wound gel

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Study Schema

Screening Phase

R A N D O M I S A T I O N

Follow-up Phase (Average follow-up 18 months)

Control (mupirocin) (n = 185)

Medihoney™ (n = 185)

Composite outcome: time to first episode of exit site infection, tunnel infection or peritonitis (whichever comes first).

AUSTRALASIAN KIDNEY TRIALS NETWORK

Rationale

- Primary failure of arterio-venous fistulae (AVF) occurs because of early thrombosis or failure of maturation
- Contemporary reports suggest early primary failure rates for AVF of between 20–54%
- Anti-platelet agents appear to be promising agents for the prevention of AVF thrombosis
 - Studies to date have not been definitive and few patients are routinely given aspirin or other anti-platelet agents for this purpose

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Study Design

Recruitment period : 3 years

Screening Phase

R A N D O M I S A T I O N

Treatment period : 12 weeks

Placebo (n = 300)

Aspirin (n = 300)

Fish oil (n = 300)

Aspirin and fish oil (n = 300)



Rationale

Recent studies indicate oxpentifylline may significantly improve haemoglobin levels in CKD patients with ESA- resistant anaemia

* Erythropoiesis Stimulating Agents (ESA)



Primary Objective

Determine whether oxpentifylline at a dose of 400 mg daily results in a significantly higher haemoglobin level at 4 months compared with placebo



Study design

Screening Phase

Randomisation

Observation : 4 months
Full blood counts : monthly

