The ADRENAL study: ADjunctive corticosteroid tREatment iN criticAlly ILL patients with septic shock

- Bala Venkatesh
- John Myburgh
- Simon Finfer
- Steve Webb
- Jeremy Cohen
- Rinaldo Bellomo
- Chris Joyce
- Colin McArthur
- Andy Rhodes
- Anders Perner
- Yaseen Arabi
- Dorrilyn Rajbhandri
- Parissa Glass
- Meg Harward

NHMRC  NZHRC  NIHR

THE GEORGE INSTITUTE
for Global Health

ANZICS Clinical Trials Group
Last year this time

• In the midst of the NCAT saga!!
• Study viability was under question as NSW participation was on hold

As of this morning we have enrolled 2700 patients
Comparative timelines

• Annane trial 3.5 years, n=299, 19 sites

• CORTICUS 3.5 years, n=499, 52 sites

• VASST 5 years, n=778, 27 sites

• ADRENAL 3 years, n=2700, 70 sites
Target

Estimated baseline mortality in septic shock – 33%
(ANZICS-CTG sepsis surveys / CAT study and global data)

5% ARR or 15% RRR, 90% power

Target Sample size – 3800 patients (1900 in each arm)
Update
Total number of sites

- 42 in Australia
- 8 in NZ
- **India** – 1
- Saudi – 3
- UK -13
- Ireland – Ethics approved
- Denmark 1
- HK – Ethics approved

Approximately 70 sites
Adrenal study - Recruitment graph

Number of patients enrolled

- Predicted
- Actual

Delay due to placebo

Dotted line - Projected finished time based on a monthly recruitment of 80

Arrow outlines the period during which there was a drop in recruitment because of NSW research governance issues
Recruitment by regions (Total = 2670)
Recruitment highlights

Adrenal centurions – PAH, Austin, Fiona Stanley, Royal Darwin, Nambour

Sites with > 90 enrolments– Nepean, King Abdul-Aziz, John Hunter, Liverpool, RBH

Top recruiter in each region
Australia – PAH
NZ – Wellington
UK- St. George
Saudi- King Abdul-Aziz
Denmark - Rigshospitalet

Top recruiter – statewise
QLD – PAH
NSW – Nepean
Vic- Austin
SA- Queen Liz
WA – Fiona Stanley
NT- Royal Darwin
Tas- Royal Hobart
DMC

• Duncan Young (Oxford, UK) - Chair
• Ian Roberts (London, UK)
• John Marshall (Toronto, Canada)

1st interim analysis completed at 950 patients

2nd interim analysis – June’16
Substudies

• ADRENAL – GEPS – GENE EXPRESSION PROFILING Host mRNA response – UQCCG - NHMRC project grant

• Consent substudy – Heidi Buhr and Dorrilyn (ICF $5000)

• HEA study – Kelly Thompson
ADRENAL-GEPS

• ADRENAL – GEPS – **NHMRC funded**
  (Evans, Venkatesh, Cohen, Myburgh, Finfer)
• A single set of bloods – at randomisation, no additional CRFs
• 22 hospitals in ANZ
• Deferred consent
• Additional $100 pp
• 240 patients enrolled to date.
• About 10 UK sites coming on board
Expression of interest for GEPS

• All units welcome

• Dorrilyn (project manager)
• Jason Meyer (PAH)
• Bala

or any member of the MC
Projected finish date

At the current recruitment rate of 80 patients per month, we anticipate that the 3800\textsuperscript{th} patient will be enrolled in June 2017, 90 day follow up (primary outcome) completed in September 2017 and 6 month follow up and data cleaning and database lock completed in December 2017.
When completed..

**ADRENAL will become the world’s largest septic shock study to date**

*If ADRENAL GEPS enrols close to a 1000 patients, then it will become the world’s largest SS genomic resource*
Thanks to

- All the RCs and PIs
- The Wonderful George Team
  Dorrilyn, Meg, Parisa, Kelly, Jason
  Serena and Ashleigh