



STARrrT AKI

Newsletter Issue 6: August 2017

Standard versus Accelerated Initiation of Renal Replacement Therapy in Acute Kidney Injury

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Follow STARrrT-AKI on Twitter!

STARrrT-AKI is on Twitter! Follow us on Twitter [@AkiStarrt](#) to receive updates on new site activations and enrolment status.



Visit Our Website

Visit our website [here](#) for the latest updates on the study and for access to study documents.



QxCalculate

Site coordinators are encouraged to download the QxCalculate app for STARrrT-AKI to aid with screening and randomizing patients!



A message from Sean and Ron/Un message de Sean et Ron

Dear friends,

It's been an exciting few months for STARrrT-AKI! Thanks to all of you, recruitment is proceeding at a healthy pace and we are well on our way to answering the most fundamental question in Critical Care Nephrology. We are honoured to be working with such wonderful colleagues. Over the last few months, we have accumulated many air miles travelling the world of STARrrT-AKI and we appreciate the warm hospitality we have received wherever we have visited.

A few key highlights...we received the incredible news that STARrrT-AKI was funded by the Medical Research Institute of New Zealand. A warm congratulations to Shay McGuiness, Paul Young and Rachael Parke for making this a reality! We recently released the new version of our operations and data entry manual. None of this would have been possible without the hard work of Nikita Chavda and Erika Dempsey and their immense patience with us! On a staffing note, we welcomed Jessica Marchese as our new study assistant at the Applied Health Research Centre while Nikita Chavda has been promoted to Project Lead. We are really lucky to have such dynamic professionals like Nikita and Jessica at STARrrT-AKI and you will surely enjoy working with them.

The next few months will be busy with the upcoming STARrrT-AKI kickoff meeting in Beijing on August 23. We also look forward to welcoming Scotland, Italy, Belgium, Switzerland and Brazil to the STARrrT-AKI family!

For those of you in the Northern hemisphere, we hope you are having an enjoyable summer with time to relax with family and friends. Of course, if you are in the Southern hemisphere, we hope you are enjoying the "winter" and there are no good excuses for not recruiting!

With warmest regards,
Sean and Ron

Chers amis,

On a passé quelques mois trs passionnants! Merci à vous, le recrutement se déroule à un rythme soutenue et nous sommes sur le chemin de répondre à la question la plus fondamentale dans les domaines de la nephrologie et soins intensifs. Nous sommes honorés de travailler avec de si merveilleux collègues. Au cours des derniers mois, nous avons accumulé de nombreuses miles aériennes voyageant dans le monde STARrrT-AKI et nous apprécions l'hospitalité chaleureuse que nous avons reçue partout où nous avons visité.

Quelques faits saillants ... nous avons reçu les nouvelles que STARrrT-AKI a été financé par l'Institut de recherche médicale de la Nouvelle-Zélande. Des félicitations chaleureuses à Shay McGuiness, Paul Young et Rachael Parke pour cette réussite! Nous avons récemment publié la nouvelle version de notre manuel d'opérations et le dictionnaire des données. Rien de tout cela n'aurait été possible sans le travail de Nikita Chavda et Erika Dempsey et leur immense patience avec nous! Nous avons accueilli Jessica Marchese comme notre nouvele assistante d'étude a Toronto, tandis que Nikita Chavda a été promue au responsable du projet. Nous sommes vraiment chanceux d'avoir des professionnels aussi dynamiques comme Nikita et Jessica chez STARrrT-AKI et vous apprécierez sûrement de travailler avec ellesk.

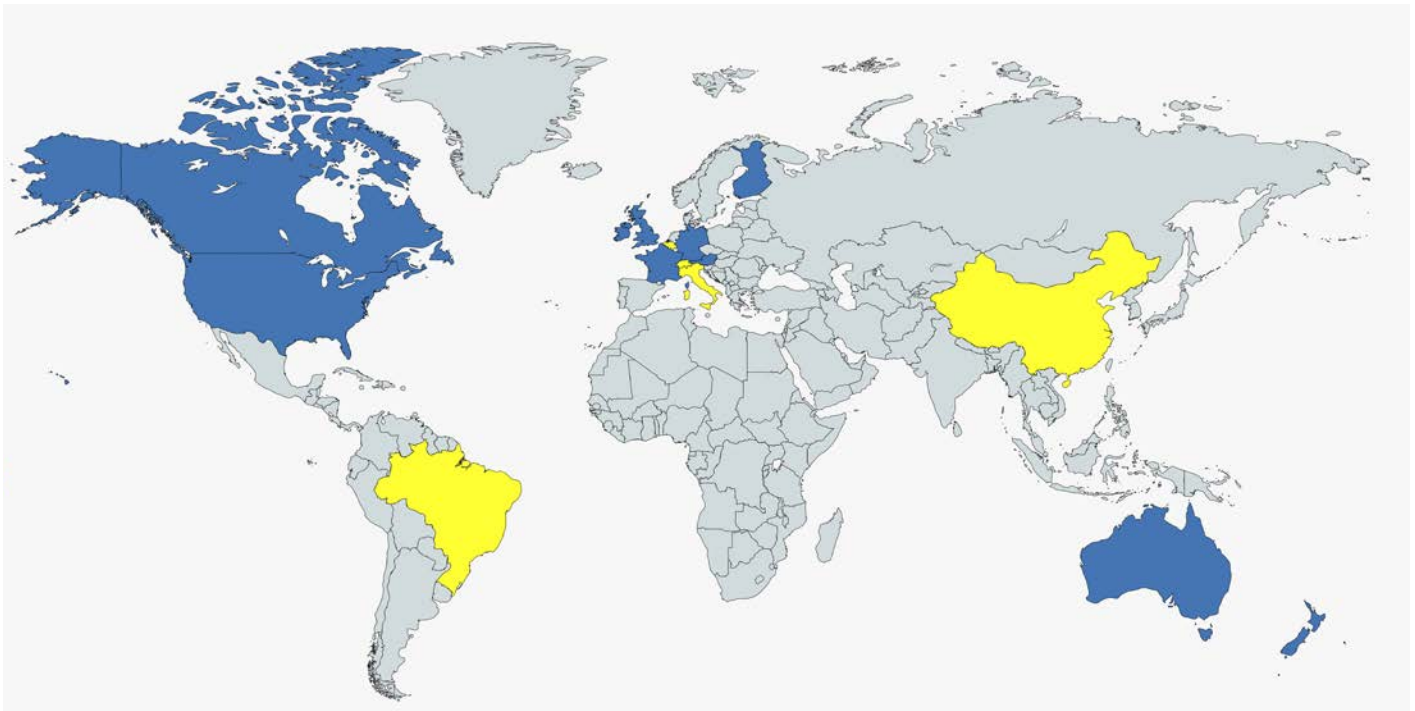
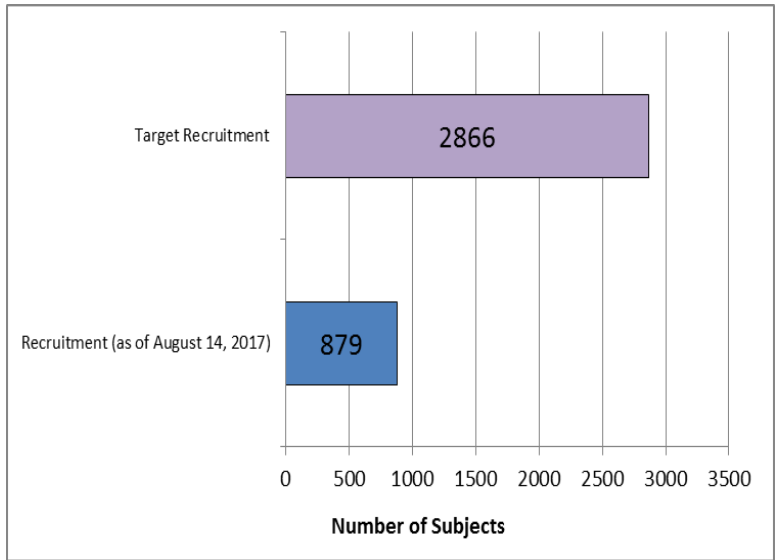
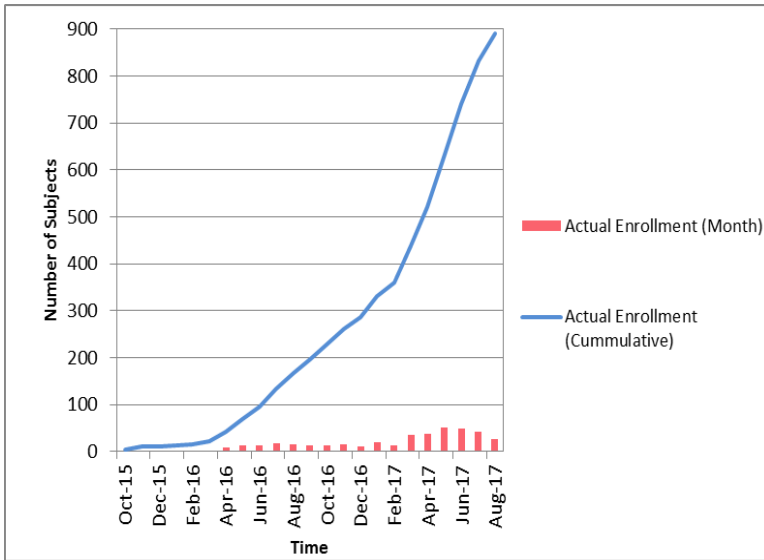
Les prochains mois seront occupés lors de la réunion de lancement STARrrT-AKI à Beijing le 23 août. Nous attendons également l'accueil de l'Ecosse, l'Italie, la Belgique, la Suisse et le Brésil a la famille STARrrT-AKI!

Pour ceux d'entre vous dans l'hémisphère nord, nous espérons que vous passerez un été agréable avec le temps de vous détendre avec votre famille et vos amis. Bien sûr, si vous êtes dans l'hémisphère Sud, nous espérons que vous apprécierez l'"hiver" et qu'il n'y a pas de bonnes excuses pour ne pas recruter!

Cordialement,
Sean et Ron

Randomization & Global Sites at a Glance

As of **August 14, 2017**, we have randomized a combined 879 subjects. Keep up the great work!



Active STARRT-AKI countries

- Canada: 39 active sites; 355 subjects
- France: 28 active sites; 303 subjects
- Australia: 11 active sites ; 136 subjects
- UK: 1 active site; 3 subjects
- Ireland: 1 active site; 2 subjects

- US: 2 active site; 9 subjects
- Germany: 1 active site; 2 subjects
- New Zealand: 3 active site; 48 subjects
- Austria: 1 site
- Finland: 3 active sites; 21 subjects

Future STARRT-AKI countries

- Switzerland
- China
- Brazil
- Belgium
- Italy
- Scotland

Study Overview and Updates

Welcome to **Medical University Innsbruck** in Austria which is our newest site activated in the month of August! As of August 9, 2017, there are **90 active sites** and **patients randomized**.

- **Recent site activations:**
 - **Australia and New Zealand:** Geelong Hospital, Bendigo Hospital, Ballarat Hospital, Eastern Health and Christchurch Hospital
 - **Europe:** St. Vincent’s University Hospital in Ireland
 - **US:** University of Alabama at Birmingham
 - **Canada:** Sturgeon Hospital and Grey Nuns Community Hospital
- **Upcoming site activations:**
 - Trillium Health Partners, Mississauga, ON, Canada
 - Additional sites in Australia and New Zealand including The Northern Hospital, Flinder Medical Centre, Concord Hospital, Royal North Shore Hospital, and Auckland Hospital Dept. of Critical Care Medicine

June 21, 2017: Dr. Ashita Tolwani visits the Applied Health Research Centre

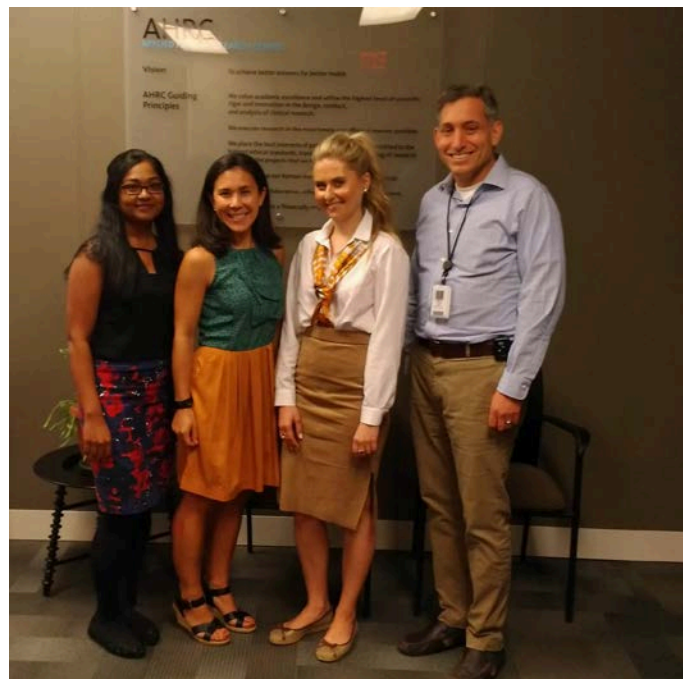


Pictured from left to right: Nikita Chavda, Ashita Tolwani (Site Investigator, University of Alabama at Birmingham), Ron Wald, and



July 6, 2017: Erika Dempsey from the George Institute visits the Applied Health Research Centre

Pictured from left to right: Nikita Chavda, Erika Dempsey (Project Manager, The George Institute, Sydney, Australia), Magda Zaporowska, Ron Wald



Updates from the Upcoming STARRT-AKI Sites

Our site members from Austria, US, Belgium, Brazil, Scotland, and Switzerland are working hard to get through the regulatory hurdles for site activation. Below is a summary of current status of the trial in each country:

- **Belgium (Prof. Eric Hoste):** Ethics approval has been obtained, and efforts are underway to finalize the contract.
- **Brazil (Dr. Fernando Thome):** Ethics approval obtained and contract review is in progress.
- **Scotland (Prof. Malcolm Sim):** Ethics is in progress and contract has been initiated
- **Switzerland (Dr. Antoine Schneider):** Ethics and contract review are in progress
- **China (Prof. Bin Du and Prof. Haibo Qui):** Ethics process nearly complete; kickoff meeting in Beijing scheduled for August 23, 2017
- **Italy (Prof. Giovanni Landoni):** Efforts submitted and contract review is underway.

Announcements

Applied Health Research Centre Staffing Update

As many of you may have already read in our announcement email, Magda Zaporowska had moved on to the management of a new portfolio of trials at AHRC. As such, Magda is no longer working on the STARRT-AKI trial. Nikita Chavda is now the Project Lead for the STARRT-AKI trial. It is also a pleasure to introduce Jessica Marchese, who is the Project Assistant for STARRT-AKI and will be supporting Nikita, Investigators and Coordinators around the world with all aspects of STARRT-AKI trial.

New Documents Released

Manual of Operations V 3.0 [25-July-2017]: We have released a new version of the Manual of Operations on July 24, 2017. The new version includes detailed instructions on data completion for each variable as well as additional information and clarifications about eligibility screening, RRT initiation and adverse event reporting. Please contact Nikita Chavda if you haven't received the updated document.

Case Report Forms V 3.0 [25-July-2017]: The new version of Case Report Forms document was released along with the Manual of Operations on July 24, 2017. CRFs V3.0 is aligned with the new STARRT-AKI database which will be released sometime in August.

Bagshaw in Brazil



*Pictured from left to right:
Patricia Scherer, Bruno
Caldin, Jose Maura Vieira
Junior, Juliane Ferreira,
Sean Bagshaw, Luis Yu
and Luciano Azevedo*



Site Profile: Red Deer Regional Hospital



Pictured from left to right: Dr. Michael Russell (Co-Investigator), Dr. Colleen Sokolowski (Co-Investigator), Carmen Peterson (Acute Care Manager) and Gillian Brown (Clinical Research Nurse)

Red Deer Regional Hospital is both excited and proud to join the STARRT AKI trial as of March 15, 2017. The response and interest from both the physician and nursing teams at Red Deer Regional Hospital has been exceptional and the team is excited to continue to enroll more patients and contribute to furthering education and research in this field. Red Deer Regional Hospital has recruited 9 patients since their activation in March!

Site Profile: Austin Hospital, Melbourne



Pictured: Professor Rinaldo Bellomo

The Austin Hospital ICU Research Office was established following the arrival of Professor Rinaldo Bellomo in 1994 with the aim of establishing an environment capable of designing, conducting and participating in local, national and international trials involving intensive care patients. Over time the ICU Research Office has developed a culture that is highly collegial, multi-disciplinary and dedicated to promoting evidence to support and improve patients care. The Austin Hospital was the first site to initiate STARRT-AKI in October 2015, and they have recruited 35 patients to date.

The Austin Hospital's ICU research team consists of: Professor Rinaldo Bellomo, ICU Director of Research; A/Prof Glenn Eastwood, ICU Research Manager; Ms. Leah Peck, ICU Research Coordinator and Ms. Helen Young, ICU Research Coordinator.

STARRT-AKI PRIDE

Congratulations to Dr. Paul Palevsky on receiving the **National Kidney Foundation Lazarus Distinguished Award!**



Congratulations to Prof. Marlies Ostermann for receiving the **Annual Vicenza Award!**



Congratulations to Dr. Sean Bagshaw on his appointment as the Chair, Critical Care Medicine, University of Alberta Faculty of Medicine and Dentistry



June 7, 2017: STARRT-AKI Meeting in Austria



Pictured from left to right: Sebastian Ulein, Prof. Thomas Staudinger, Ron Wald, Prof. Michael Joannidis and Prof. Philipp Eller.

Le 6 juin 2017: Réunion STARRT-AKI à Paris



STARRT-AKI France team hosting Ron Wald



Frequently Asked Questions (FAQs)

- **RE: Form 6 – Risk Factors, if a patient had bypass surgery and had aminoglycoside administered >7 days prior to randomization, how should we approach data entry for Risk Factor?** If cardiac bypass surgery took place > 7 days from randomization, it should not be recorded as “no”. If aminoglycosides were started > 7 days before randomization but the patient received at least 1 dose within the window of 7 days prior to randomization, then please record “yes”.
- **RE: Daily data, if a patient had mixed venous labs, can we use these values for the daily pH and PaO2/FiO2 ratios?** For daily data, mixed venous should **not** be used as value of PaO2 because it is not arterial. If no arterial blood gas was done for determination of an arterial oxygen tension, then we suggest using the Appendix for Pulmonary System Conversions that is found in the operations manual. Look at the lowest oxygen saturation of the day and convert this to PaO2. Calculate the PaO2/FiO2 by taking the FiO2 recorded at the time the lowest SaO2 was detected.
- **If a patient experienced an adverse event during RRT, but it is deemed by the Site Investigator as not being related to RRT or other study related procedures, should we record this event on the CRFs?** No, since for this trial we are only collecting events which are related to the study procedures, events which are not related to the study procedures would not be recorded on the CRFs even though it might have occurred during RRT.

Site Reminders

Screening Logs and Form 3

For sites which are actively screening, please remember to submit your screening logs to the Coordinating Centre on a monthly basis. Form 3 should be submitted on a quarterly basis.

Database Queries

This is a gentle reminder to all the sites to ensure that data are entered and queries answered in a timely manner. For any database related questions, please contact Nikita Chavda (ChavdaN@smh.ca).

Study Contacts			
Coordinating Centre		Principal Investigators	
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