

# STARRT-AKI

Newsletter Issue 3: November 2016

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

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### A message from the Principal Investigators

Dear STARRT-AKI Team Members,

We are excited to share that our team continues to grow with new sites being initiated across Canada, the United States, and Ireland. We are now 35 sites! We look forward to welcoming new sites very soon from across Europe and Asia.

In addition to following us on Twitter (@Akistarrt), we are happy to share the launch of our new STARRT-AKI website: ([www.ualberta.ca/critical-care/research/current-research/starrtaki](http://www.ualberta.ca/critical-care/research/current-research/starrtaki)). We aim for this to be an important resource and repository for STARRT-AKI-related information and updates. Please check it out and let us know what you think!

In the meantime, we are grateful for your continued commitment effort to STARRT-AKI.

Sincerely,

Ron and Sean

### Study Overview

Thank you for your ongoing efforts and enthusiasm toward STARRT-AKI trial! Below is an overview of the current overall status of STARRT-AKI:

- As of November 24, 2016 there are 255 patients in total enrolled in STARRT-AKI
- There are currently 38 active sites in Canada, Australia, New Zealand, Finland, Ireland, and US
- **Recent site activations:**
  - St. Vincent's University Hospital (Dublin, Ireland)
  - Mayo Clinic (Rochester, US)
  - Surrey Memorial Hospital, Fraser Health (Surrey, BC)
  - Victoria General Hospital and Royal Jubilee Hospital (Victoria, BC)
  - Foothills Hospital (Calgary, AB)
  - Peter Lougheed Centre (Calgary, AB)
  - University Health Network (Toronto, ON)
- **Upcoming site activations:**
  - McGill University (Montreal, QC)
  - University Munster Hospital (Germany)

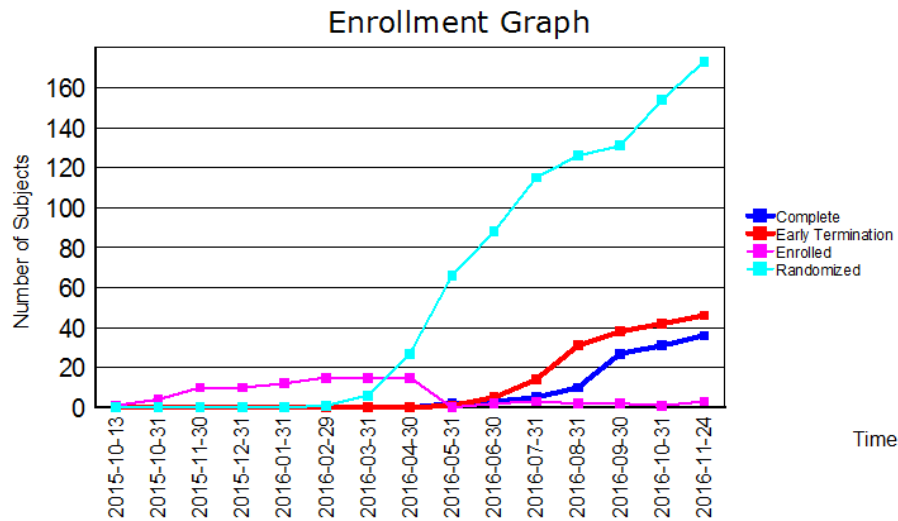
### Follow STARRT-AKI on Twitter!

STARRT-AKI is on Twitter! Follow us on Twitter [@Aki-Starrt](https://twitter.com/Aki-Starrt) to receive updates on new site activations and enrolment status.



Enrollment Report for STARRT-AKI - Prod

24 Nov 2016



Site Specific Updates

Welcome to Mayo Clinic in United States which is the newest site activated in the month of November! The table below provides a breakdown of the number of active sites by country. For a full list of names of active sites, please visit the STARRT-AKI trial on [ClinicalTrials.Gov](http://ClinicalTrials.Gov).

Country	Number of active sites
Canada	26
US	1
Australia	7
New Zealand	2
Finland	1
Ireland	1

Updates from the Upcoming STARRT-AKI Sites

Our collaborators from Austria, Belgium, France, Germany, US, and the UK 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:

- **Austria (Dr. Michael Joannidis):** Efforts underway to obtain REB approval and finalize the contract.
- **Belgium (Dr. Eric Hoste):** Contract and Ethics application are currently in progress.
- **France (Drs. Didier Dreyfuss & Stephane Gaudry):** Ethics and contract are both in progress.
- **Germany (Dr. Alex Zarbock):** Ethics approval is in place and the site has received protocol training. Site is awaiting contract and start up documents required for site activation.
- **UK (Dr. Marlies Ostermann):** Contract has been finalized and initiated for signatures, REB application will be submitted once the contract has been fully signed and executed.



## Announcements

### STARRT-AKI Website

We are excited to announce the launch of STARRT-AKI website: <https://www.ualberta.ca/critical-care/research/current-research/starrtaki>. On this website, you will find study related information and documents including the most recent version of the protocol, consent form template, manual of operations, newsletters, and up-to-date enrolment data. Be sure to check out the website and let us know your thoughts!

### Enrolment Reports and Tips

We are circulating weekly enrolment reports along with enrolment and data entry tips. If you haven't been receiving the reports, please email Magda Zaporowska ([ZaporowskaM@smh.ca](mailto:ZaporowskaM@smh.ca)). For more enrolment tips, stay tuned and look out for the weekly enrolment reports in your inbox! If you have any tips that you think might be helpful for your fellow Study Coordinators, shoot us an email and we will be glad to circulate!

### Document updates

We are currently working towards updating the Manual of Operations and we hope to release V3.0 of this document in the New Year. In the upcoming version of the Manual of Operations, we aim to address all the questions and concerns that we have received from the Study Coordinators. Stay tuned for the updates!

## Ron visits the STARRT-AKI team at Centre hospitalier de l'Université de Montreal in Montreal, Canada



Left to right: Ron, Martine Lebrasseur (Research Coordinator, CHUM), Dr. Pierre Aslanian (ICU, CHUM)



Left to right: Ron, Fatna Bennatib (Research Coordinator, CHUM), Dr. Francois Carrier (ICU, CHUM)

## Site Profile: Auckland City Hospital (New Zealand)

The Cardiothoracic and Vascular Intensive Care Unit is located at Auckland City Hospital. Auckland is the largest city in New Zealand and home to over 1.4 million people – 32% of the nation's population.

Auckland is built around two beautiful harbours, many beaches and straddles the Auckland volcanic field which contains 50 extinct (we hope) volcanoes.

Auckland City Hospital is New Zealand's largest public hospital. It is located in the central business district and has 710 beds. The hospital is the national referral centre for complex cardiac surgery, heart and lung transplantation and ECMO.

CVICU Research has a strong interest in acute kidney injury and we are excited to have them as part of the STARRT-AKI team.

*Pictured from left to right: Dr. Shay McGuinness (PI), Eileen Gilder, Dr. Rachael Parke, Jane Dalton, Magdalena Butler, Keri-Anne Cowdrey, Stephnie Long, Aimee Blakemore, Dr. Mike Gillham (Intensivist)*



## STARRT-AKI Investigator Meeting at CCCF Conference 2016

We had the pleasure of meeting some of you in person at the STARRT-AKI Investigator Meeting at CCCF Conference in Toronto! Thank you to all the attendees for taking the time out of your busy schedules to attend the meeting. For those who were unable to attend CCCF, we will have regular meetings at major Critical Care and Nephrology conferences in the future. To find out about any upcoming STARRT-AKI Investigator Meetings, please contact Nikita Chavda ([ChavdaN@smh.ca](mailto:ChavdaN@smh.ca)) or see our website for updates <https://www.ualberta.ca/critical-care/research/current-research/starrtaki>.





## Frequently Asked Questions (FAQs)

- ❖ **What period constitutes the cumulative fluid balance up to the time of RRT Initiation?** This information should reflect the total fluid balance from the beginning of the current ICU admission until the day RRT commenced. Please note the cumulative balance recorded in the patient’s chart up to the day *preceding* the commencement of RRT. As an example, consider a patient who was admitted to the ICU on November 15 and commenced RRT at 8:00 am on November 17. Assuming that the ICU records information on calendar days (ie, end of “ICU day” occurs at 11:59 pm), please record the cumulative fluid balance as of 11:59 pm on November 16.
- ❖ **A patient was deemed eligible for the trial; however, was later discharged as he recovered and did not end requiring dialysis. The same patient was now readmitted to the ICU; however, the patient is only provisionally eligible as the clinician caring for the patient believes that deferral of RRT is mandated and the patient will again recover. If the patient remains in the ICU and does continue to progress, will he be eligible for the study?** Patients with recurrent AKI are eligible for the study. If the patient’s AKI worsens/persists and the clinician changes his/her mind with respect to the current view that the patient will recover, the patient can be included. If a provisionally eligible patient was excluded due to exclusion 10, we encourage site coordinators to ask clinicians whether their initial view that RRT deferral is mandated is still in effect (assuming all other eligibility criteria are still met).

## Site Reminders

### Monthly Coordinator Calls

The next coordinators call will be held on November 29<sup>th</sup>, 2016. This is a great chance to connect with Study PIs and the Coordinating Centre and ask questions. If you haven’t received an invitation for these calls, please contact Magda Zaporowska at [ZaporowskaM@smh.ca](mailto:ZaporowskaM@smh.ca).

### Database Queries

A gentle reminder to all the sites to ensure that data is entered and queries are answered in a timely manner. For any database related questions, please contact Nikita Chavda ([ChavdaN@smh.ca](mailto:ChavdaN@smh.ca)) or Magdalena Zaporowska ([ZaporowskaM@smh.ca](mailto:ZaporowskaM@smh.ca)).

### Site Contact List

Please provide us with any staffing updates that occur at your site throughout the course of the trial. If you have new Investigators and/or Study Coordinators involved in the trial, please provide us with their contact information so we can keep them up-to-date on the trial status.

Study Contacts			
Coordinating Centre		Principal Investigators	
Magda Zaporowska, Project Lead Email: ZaporowskaM@smh.ca Phone: 416-864-6060 ext. 76210	Nikita Chavda, Study Assistant Email: ChavdaN@smh.ca Phone: 416-864-6060 ext. 7893	Ron Wald Email: WaldR@smh.ca Phone: 416-867-3703 Cell: 416-258-6540	Sean Bagshaw Email: Bagshaw@ualberta.ca Office: 780-492-3817 Cell: 780-722-9756