

STARRT-AKI

Newsletter Issue 2: July 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:

It has been an exciting few months for the STARRT-AKI Program. The trial has truly expanded in so many ways. New sites are being activated almost weekly with many more on the way. It has been especially rewarding to meet so many of you through our SIV sessions. Though the webinars have been fun, nothing is better than an on-site visit to really get an understanding of the wonderful work that you do and your dedication to helping improve the care of critically ill patients with AKI. We look forward to having more site visits as well as opportunities to meet you at "STARRT-AKI Team Meetings" that will be held during major critical care and nephrology conferences.

Our STARRT-AKI family has many members all over the world. We hope that this newsletter will serve as a medium that will help better connect us all. For those of you on Twitter, you can follow us at @akistarrt. Stay tuned for the launch of the trial website!

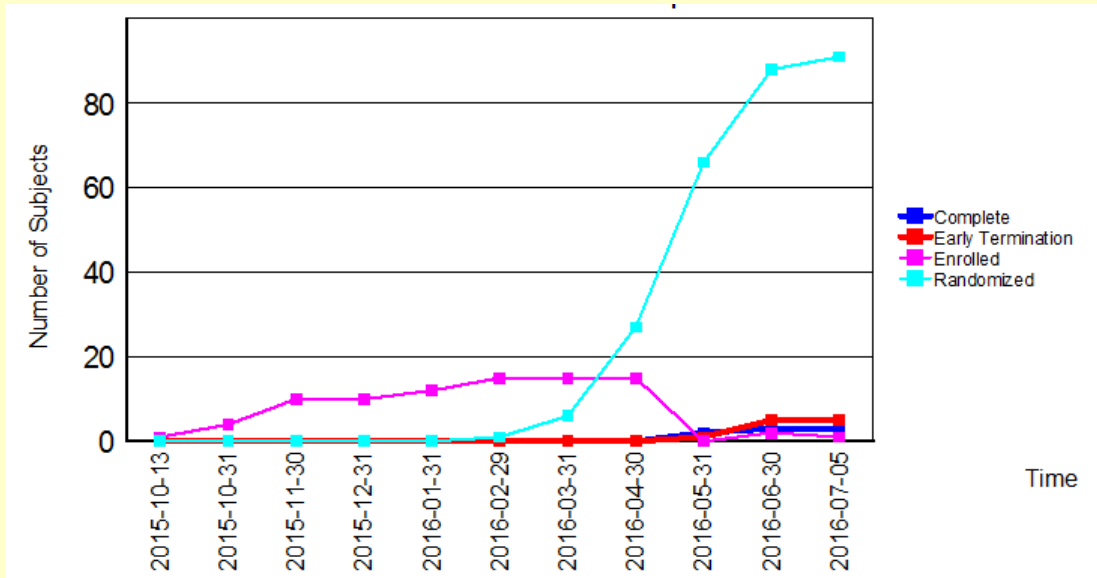
Release of the ELAIN and AKIKI trials (in JAMA and NEJM, respectively) have thrust the topic of RRT timing in AKI to the forefront of discussion in critical care nephrology. The STARRT-AKI program was cited in both these papers and members of our steering committee have written several invited commentaries on these studies. We will share these with you as they are published. The bottom line is that the discordant findings of these landmark trials make the need to complete STARRT-AKI more urgent than ever.

We are grateful to all of you for your tireless efforts on behalf of STARRT-AKI. We extend a special thanks to our excellent team at the Applied Health Research Centre, Magda Zaporowska (Magda recently joined us and replaces Shristi who is on leave) and Nikita Chavda. For those of you in the Northern hemisphere, we wish you a restful summer and hopefully some well-deserved time off. To our friends in Australia and New Zealand, keep warm and dry this winter but consider a trip to Canada in January to see what a real winter is.

Ron and Sean

Enrolment Updates

We are pleased to see that enrolment in the STARRT-AKI trial has increased in the last couple of months. Congratulations to Kingston General Hospital for enrolling their first patient in the month of June! As of July 05, 2016, 24 active sites have enrolled 100 patients. Thank you for your ongoing efforts and enthusiasm toward STARRT-AKI! We hope that you would enroll at least 2 patients per site/month to meet the goal of study completion in 4 years. The graph below provides an overview of the enrollment progress since the first patient was randomized in October 2015.



Site Updates

Welcome to Sunnybrook Health Sciences Centre, Hôpital Maissoneuve Rosemont, and Regina Qu’Appelle Health Authority which are the newest sites activated in the month of June! We look forward to bringing on board many other sites from around the world. The total number of active sites worldwide as of today is 25. 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.

| Country | Number of active sites |
|-------------|------------------------|
| Canada | 16 |
| Australia | 6 |
| New Zealand | 2 |
| Finland | 1 |

What’s next for STARRT-AKI?

We are excited to bring sites from Austria, Ireland, Germany, France, US, and China on board. As we work our way through regulatory hurdles to bring more sites on board, below is a summary of current status of the trial in each country:

- **UK (Dr. Marlies Ostermann):** Contract is currently in progress, REB application will be submitted once the contract is in place.
- **Austria (Dr. Michael Joannidis):** Efforts underway to obtain REB approval and finalize the contract.
- **Ireland (Dr. Alistair Nichol):** Received full REB approval, efforts underway to finalize the contract.
- **US, Mayo Clinic (Dr. Kianoush Kashani):** Ethics application and contract are both in progress.
- **Belgium (Dr. Eric Hoste):** Contract and Ethics application are currently in progress.

Frequently Asked Questions (FAQs)

- ❖ If a patient expires, should I record this as an Adverse Event on the eCRF? Death alone would not qualify as an AE/SAE; it would need to have been related to dialysis, vascular access, or some other trial related activity in some way in order to be reportable.
- ❖ If a patient comes in for heart surgery, and has intraoperative dialysis, would they be excluded from being enrolled to the trial according to Exclusion Criteria #5? Intraoperative dialysis alone is not considered as an event that would qualify for exclusion 5.
- ❖ If a patient has a creatinine value taken prior to their current hospitalization but it is taken during an ER visit, does this count as an outpatient sCr that can be used as a baseline? Or should the lowest sCr during the current hospitalization be used instead? It may be used as long as it is not the ER visit at the current hospitalization.
- ❖ What period of time constitutes Day 0 and when should data for this day be collected? Day 0 commences at the time of randomization and ends when the "ICU day" ends. In an ICU where the day runs from 8 am-7:59 am, a patient randomized on July 6 at 22:00 will have day 0 run from 22:00 on July 6 until July 7 at 7:59. Day 1 will then be 8:00 on July 7 until 7:59 on July 8. Please refer to the Operations Manual (V 2.0) for further details.

Site Reminders

Monthly Coordinator Calls

The first monthly coordinator call for Canadian sites was held on March 31st, 2016. These calls will be held on last Tuesday of every month (2-3 PM Eastern Time), and their purpose is to address any questions or issues that STARRT-AKI Study Coordinators may be facing, and to receive feedback from sites. If you haven't received an invitation for these calls, please contact Magda Zaporowska at ZaporowskaM@smh.ca. Next call will be held on July 26th.

Screening Logs

For sites which are actively screening, please remember to submit your screening logs to the Coordinating Centre on a monthly basis.

Updated Documents

The study Operations Manual has been finalized, and the final version (Version 2.0) was circulated on July 05, 2016. If you haven't already received it, please contact Nikita Chavda (ChavdaN@smh.ca).

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. This account is managed by Dr. Sean Bagshaw.

Screening Tool for STARRT-AKI

In collaboration with QxMD and Dr. Daniel Schwartz, we have developed a screening tool which Coordinators and Site Investigators will be able to access from their mobile devices! We would like to thank Dr. Daniel Schwartz for his time and effort in making this happen. This screening tool will allow site members to determine patient's eligibility for the trial by simply answering eligibility questions on their phone. This app also provides links to the trial pocket cards and Medidata RAVE. To access this app, download Calculate by QxMD on your phone or desktop, and after you have signed up search for "STARRT-AKI Enrollment. Please refer to the Operations Manual (Version 2.0) for detailed guidelines on how to use this app.

Triple Play!

The research team at St. Paul's Hospital (Vancouver, Canada) made STARRT-AKI history on July 6 by randomizing 3 patients in the span of 26 minutes! Kudos to the lead coordinator Victoria Alcuaz and site PI Peter Dodek.

From left to right: (first row) Mindy Gross, Dr Erasmus Okello, Victoria Alcuaz, Mia Marles, Sim Sunner, Ron Bernardo, (second row) James Wu, Kiley Dempsey and Jason Kent.



Dr. Sean Bagshaw at International Renal Research Institute of Vicenza (IRRIV)



Your Team at AHRC!

Nikita Chavda (left) and Magda Zaporowska (right) are your primary contacts at the Coordinating Centre for any trial related questions.



Site Profile: Kingston General Hospital, ON (Canada)

Kingston General Hospital (KGH) is a community of people dedicated to transforming the patient and family experience through innovative approaches to care, knowledge, and leadership. KGH was activated for STARRT-AKI trial on April 25, 2016 and have recruited their first patient in June 2016. Congratulations to the team!

Picture below - from left to right: Dr. John Muscedere (Intensivist at KGH), Dr. Gordon Boyd (Neurologist, Intensivist and Clinician Scientist), Ilinca Georgescu (ICU Research Coordinator), Miranda Hunt (ICU Research Coordinator) and Dr. David Maslove (Clinician Scientist, and an Intensivist at KGH).



Study Contacts

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