

STARRT-AKI

Newsletter Issue 4: December 2016

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



Dear STARRT-AKI Team,

Over the past year we have witnessed the expansion of STARRT-AKI in many cities, countries and continents. Next year promises to be an exciting one as we launch the trial throughout Europe and China will continue expanding the trial in North America, Australia and New Zealand. Though we are still early in the trial, we are all motivated by the goal of finally answering a vital question in Critical Care Nephrology. Our success to date would not have been possible without your hard work and tireless dedication. We thank you for all that you do on behalf of the trial.

Please accept our warmest wishes for the holiday season. May 2017 be filled with health, happiness and success for you and your loved ones.

With warmest regards,

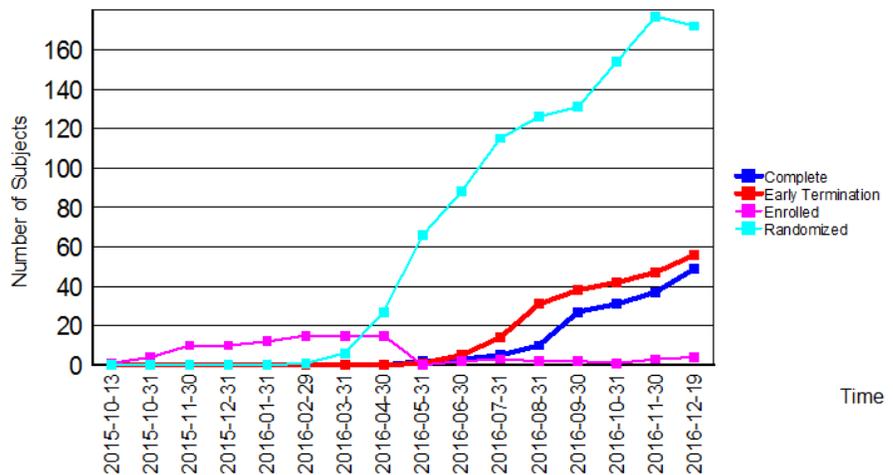
Sean and Ron

Inside This Issue



- 1 A message from the Principal Investigators
- 1 Recruitment at a Glance
- 2 Study Overview and Updates
- 2 Site Reminders and Announcements
- 3 FAQs
- 4 Contact Us

Recruitment at a Glance



Time

Study Overview and Updates

Welcome to McGill University Health Centre in Canada which is the newest site activated in the month of December! As of December 22, 2016, there are currently **39 active sites** and **280 patients randomized**. 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	27
US	1
Australia	7
New Zealand	2
Finland	1
Ireland	1

Reminders and Announcements

Forgot your RAVE Password?

In case if you forget your password in the future, you can easily reset it using your PIN number by clicking on the 'forgot password' link on RAVE's login page. Your PIN number is the 4-digit number that you had provided on your RAVE account activation form. Please note that RAVE will automatically lock you out if you have had 3 failed attempts at logging into your account. In order to avoid being locked out, please ensure that you reset your password after the second failed attempt at logging in.

Data Entry

Please update data entry on RAVE for **all** patients randomized at your site by the end of the calendar year. We expect the first DSMB meeting to take place at the beginning of 2017. For this meeting, the DSMB Chair has requested a report detailing the flow of screening, baseline patient demographics and adverse events. So bringing your site data up to date would be greatly appreciated!

Site Payments

The first quarterly payment reports for 2017 will be run on the week of January 23, 2017. Please ensure that you have answered all the queries issued by our Data Manager as we will not be able to process payments for any patients with outstanding queries on the database. Deadline to answer all your outstanding queries is January 06, 2017.

Ron visits the STARRT-AKI team at Mayo Clinic, US (left picture) and McGill University, Canada (right picture)



Ron with the team at Mayo Clinic, US



Ron with the team at McGill University Health Centre, Canada

Frequently Asked Questions (FAQs)

- ❖ **If a patient is re-screened multiple times, how is this entered on the screening log?** Each patient should only be entered on the screening log one time once a final decision about the study inclusion has been made.
- ❖ **If a patient is randomized to the standard/delayed arm and starts RRT 11hours and 45minutes after the time of full eligibility, is this considered a protocol deviation?** Yes, if the patient was randomized to the standard/delayed arm and starts RRT less than 12 hours after the time of full eligibility, this should be entered as a protocol deviation.
- ❖ **What classifies filling out Form 11? If RRT was stopped at one point during the day and then reinitiated later that day, is that a new RRT initiation, or does RRT have to stop for more than 24 hours to be classed as a new RRT initiation?** If RRT was stopped at one point during the day and then reinitiated later that day, then it is NOT considered to be a new RRT initiation.
- ❖ **Form 9 Pre-randomization data: In the paper CRF, we can encircle +/- fluid balance, but we cannot include the + sign in the online data entry as it is giving us alert, so do we just enter the actual fluid balance without the sign?** Yes, for positive fluid balance values please enter the fluid balance without the sign.

Site Profile: Centre Hospitalier Universitaire de Sherbrooke (CHUS)

CHUS is the fourth largest hospital in Quebec and local hospital for residents in Sherbrooke. CHUS has provided ultra-specialized care in cardiology, neurosurgery, medical and surgical oncology, and neonatology to people from the Centre-du-Québec and part of the Montérégie regions, and offers services to about one million people. CHUS has been a part of STARRT-AKI trial since March 2016 and has recruited 24 patients so far! Thank you to the team for your hardwork.

Left to right: Elaine Carbonneau (Team Management, Registered Nurse); Marie-Helene Masse (ICU Research Coordinator); Virginie Bolduc (Registered nurse and ICU research coordinator); Joannie Marchand (Research Assistant)



Study Contacts

Coordinating Centre		Principal Investigators	
<p>Magda Zaporowska, Project Lead 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>Ron Wald Email: WaldR@smh.ca Phone: 416-867-3703 Cell: 416-258-6540</p>	<p>Sean Bagshaw Email: Bagshaw@ualberta.ca Office: 780-492-3817 Cell: 780-722-9756</p>