

STARrrT AKI

Newsletter Issue 8: March 2018

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



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A Message from Sean Bagshaw and Ron Wald

Dear STARrrT-AKI Team members,

We hope you are all well! Spring has arrived in Canada which means that we are starting to de-frost! The last few months have been very gratifying and productive for STARrrT-AKI. Here are some of the highlights. We were extremely fortunate to receive a third operating grant from the Canadian Institutes of Health Research. This funding was a big relief as it will provide the financial support to enable completion of recruitment. We also brought a new continent into the STARrrT-AKI fold as the first patients in China were recruited. A warm thanks goes to our incredible team at the George Institute office in Beijing and our Chinese investigators led by Professor Bin Du. We were also thrilled to welcome our first Belgian site, Ghent University Hospital. Thanks to all of you, enrollment continues to progress steadily, and we crossed the 50% mark for recruitment in January. Finally, we are extremely grateful to those of you who have hosted us in recent months during site initiation visits, specifically Professor Giovanni Landoni in Milan and Dr. Sairah Sharif in Providence, Rhode Island. It is a true privilege to visit new hospitals and meet colleagues who are so enthusiastic and engaged.

The priorities for the next few months will be the further expansion of the trial at sites in the United Kingdom, China, Switzerland, Italy and Kenya. We are also working on the publication of our trial protocol. Finally, we are gearing up for our next interim analysis (the one triggered by enrolling 50% of the planned trial population) sometime this summer.

Thank you again for your dedicated support of STARrrT-AKI. As always, feel free to reach out to us anytime with any questions.

With warmest regards,
Sean and Ron

Chers membres de l'équipe STARrrT-AKI,

Nous espérons que vous allez tous bien! Le printemps est arrivé au Canada, ce qui signifie que nous commençons à dégeler! Les derniers mois ont été très gratifiants et productifs pour STARrrT-AKI. Voici quelques "faits saillants". Nous avons été extrêmement chanceux de recevoir une troisième subvention des Instituts de recherche en santé du Canada. Ce financement a été un grand soulagement car il fournira le soutien financier nécessaire pour permettre l'achèvement du recrutement. Nous avons également introduit un nouveau continent à la famille STARrrT-AKI au moment où les premiers patients chinois ont été recrutés. Un grand merci à notre incroyable équipe du bureau de l'Institut George à Beijing et à nos enquêteurs chinois dirigés par le professeur Bin Du. Nous avons également été ravis d'accueillir notre premier site belge, l'hôpital universitaire de Ghent. Grâce à vous tous, les inscriptions continuent de progresser régulièrement et nous avons franchi la barre des 50% pour le recrutement pendant le mois de janvier. Finalement, nous sommes extrêmement reconnaissants à ceux d'entre vous qui nous ont accueillis ces derniers mois lors des visites d'initiation du site, en particulier le Professeur Giovanni Landoni à Milan et le Dr Sairah Sharif à Providence, Rhode Island. C'est un vrai privilège de visiter de nouveaux hôpitaux et de rencontrer des collègues qui sont si enthousiastes et engagés.

Les priorités pour les prochains mois sont l'expansion de STARrrT-AKI au Royaume-Uni, en Chine, en Suisse, en Italie et au Kenya. Nous travaillons également sur la publication de notre protocole. Enfin, nous nous préparons pour la prochaine analyse intermédiaire (celle déclenchée par l'inscription de 50% de la population d'essai prévue) cet été.

Merci encore pour votre soutien dévoué à STARrrT-AKI. Comme toujours, n'hésitez pas à nous contacter à tout moment pour toute question.

Cordialement,
Sean et Ron

Follow STARrrT-AKI on Twitter!



STARrrT-AKI is on Twitter!
Follow us on Twitter [@STARrrTAKI](#).

Visit Our Website!



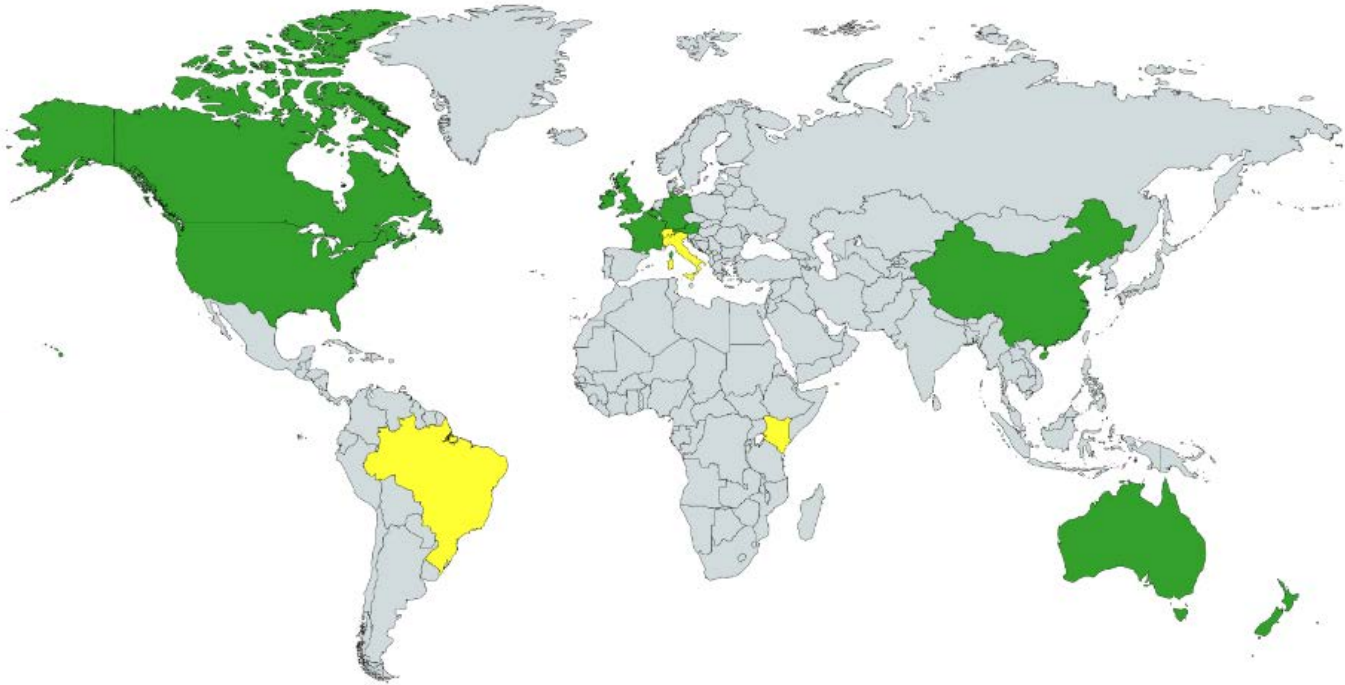
Visit our website [here](#) for the latest updates on the study and for access to study documents.

QxCalculate



Investigators and coordinators are welcome to download the FREE QxCalculate app (available on all smartphone operating systems) which includes interactive tools to aid in screening and randomizing patients for STARrrT-AKI.

The World of STARRT-AKI



Active STARRT-AKI countries

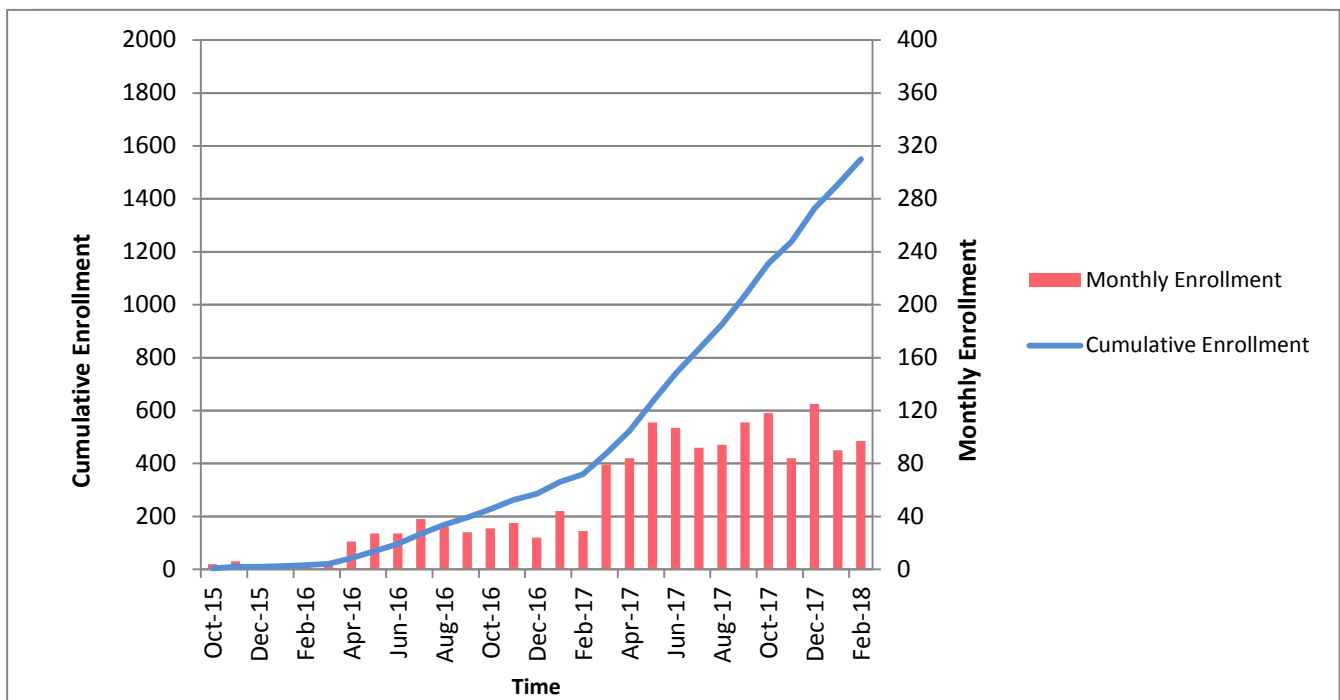
- Canada: 42 active sites; 547 subjects
- France: 29 active sites; 708 subjects
- Australia: 14 active sites ; 211 subjects
- UK: 1 active site; 21 subjects
- Ireland: 1 active site; 3 subjects
- Belgium: 1 active site; 7 subjects

- US: 4 active sites; 31 subjects
- Germany: 2 active site; 11 subjects
- New Zealand: 5 active site; 75 subjects
- Austria: 2 sites; 15 subjects
- Finland: 3 active sites; 37 subjects
- China: 8 active sites; 5 subjects

Soon to Join STARRT-AKI

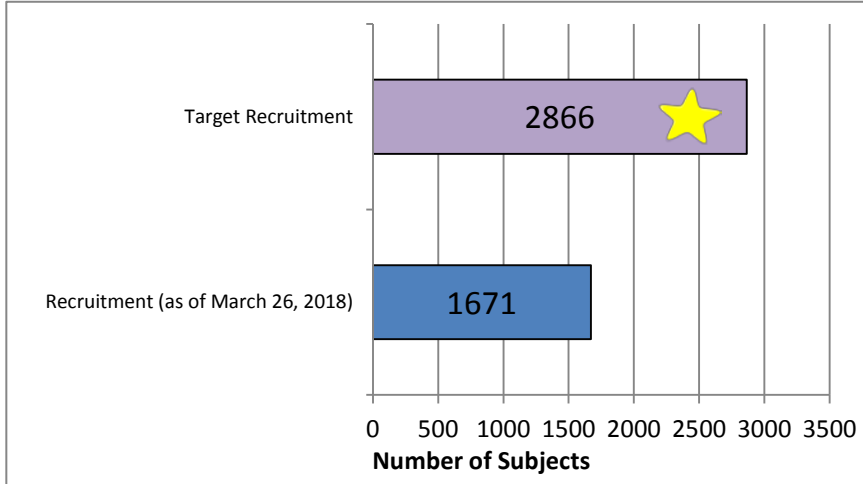
- Switzerland
- Kenya
- Brazil
- Italy

Cumulative Enrollment as of February 2018



Recruitment Status

As of March 26th, 2018, we have randomized **1671** subjects. Thank you to all the sites for your dedication and hard work.



Announcements

Manual of Operations Version Update

We are in the process of revising a new version of the Manual of Operations to aid with a more efficient data collection! The changes will be reflected in the collection of AEs and SAEs, providing a more straight-forward and simple approach to recording this data.

2nd Interim Analysis

Our first interim analysis was reviewed at our DSMB meeting in early January 2018 and it was a success! Since we recently crossed the 50% recruitment mark, we are in the process of preparing for our next interim analysis. We would like to thank all the sites for their ongoing diligent data entry and hard work!

CIHR Grant Fall 2017

The STARRT-AKI study was approved for full CIHR funding in January 2018!

Study Overview and Updates

Welcome to **Shandong Provincial Hospital** in China, which is our newest site activated in the month of March! As of March 26th, 2018, there are **112 active sites** and **1671 patients randomized**.

Recent site activations:

- *Belgium*: Ghent University Hospital (Ghent)
- *Canada*: Health Sciences Centre (Winnipeg)
- *China*: Beijing Friendship Hospital (Beijing), Guizhou Provincial People's Hospital (Guiyang), Henan Provincial People's Hospital (Zhengzhou), Renmin Hospital of Wuhan University, The First Affiliated Hospital of Xi'an Jiaotong University (Xi'an), Zhongda Hospital Southeast University (Nanjing), Xiangya Hospital Central South University (Changsha), Shandong Provincial Hospital (Jinan)
- *Germany*: Klinikum Coburg (Coburg)
- *New Zealand*: Rotorua Hospital (Rotorua)
- *USA*: University of Florida (Gainesville)

Upcoming site activations:

- *Australia*: The Northern Hospital (Melbourne), Concord Hospital (Sydney)
- *Brazil*: Hospital de Clínicas de Porto Alegre- Rio grande do Sul (Porto Alegre)
- *China*: Peking Union Medical College Hospital (Beijing), The First Hospital of Jilin University (Changchun), The First Affiliated Hospital of Xiamen University (Xiamen), Zhongnan Hospital of Wuhan University (Wuhan)
- *Italy*: San Raffaele Hospital (Milan)
- *Kenya*: Aga Khan University Hospital Nairobi (Nairobi)
- *Scotland*: Queen Elizabeth University Hospital (Glasgow), Ayr Hospital (Ayr), Golden Jubilee National Hospital (Clyebank), Aberdeen Royal Infirmary (Aberdeen), Hairmyres Hospital (East Kilbride), Monklands District General Hospital (Airdrie)
- *Switzerland*: Centre Hospitalier Universitaire Vaudois, CHUV (Lausanne)
- *UK*: King's College Hospital (London), Lewisham Hospital (London), Princess Royal University Hospital (London), Wycombe Hospital (Buckinghamshire), Liverpool University Hospital (Liverpool), Nottingham University Hospital (Nottingham), Leeds Teaching Hospital (West Yorkshire), Stoke Mandeville Hospital (Aylesbury)
- *USA*: Rhode Island Hospital (Providence)

STARRT-AKI Team Pictures

San Raffaele Hospital
Milan, Italy
February 20, 2018



Pictured left to right: Claudia Frassanito, Martina Baiardo, Stella Sordani, Omar Saleh, Dr. Giorgio Slaviero, Prof. Giovanni Landoni, Dr. Evgeny Fominsky, Dr. Giacomo Monti, Giuseppe Dalessandro, Alessandro Belletti and Ron Wald

Rhode Island Hospital
Providence, Rhode Island
January 25, 2018



Pictured left to right: Ron Wald, Stephanie Warren, Matthew Lynch, Sairah Sharif, Gerard Carino and Jason Aliotta

The joy of randomizing the first STARRT-AKI patient!
Ghent University Hospital, Ghent, Belgium
March 6, 2018



Pictured left to right: Prof. Eric Hoste and Stephanie Bracke

STARRT-AKI Investigators hard at work at AKI & CRRT 2018 in San Diego, California



Pictured left to right: Kianoush Kashani (Mayo Clinic) and Sean Bagshaw



Pictured left to right: Javier Neyra (University of Kentucky) and Sean Bagshaw



Pictured left to right: Marlies Ostermann (Guy's and St. Thomas), Sean Bagshaw and Ashita Tolwani (University of Alabama Birmingham)



Pictured left to right: Sean Bagshaw and Azra Bihorac (University of Florida)

STARRT-AKI Site Profile

The University of Kentucky (Lexington, Kentucky, USA)

The University of Kentucky Albert B. Chandler Hospital is a 945-bed academic facility located in Lexington, Kentucky, United States. It is one of the nation's finest academic health care centers. Its vision is to be a top-20 academic health center recognized nationally and internationally for excellence in teaching, research and patient care. The University of Kentucky joined the STARRT-AKI team early in 2018 and recruited their first patient in February 2018. Thus far, they have 10 patients, an incredible achievement!



Pictured left to right: Dr. Juan Carlos Aycinena (Co-Investigator), Dr. Javier A. Neyra (Principal Investigator), Madona Elias (Clinical Research Coordinator), Robert Dorfman (Research Nurse), and Dr. Victor Ortiz-Soriano (Research Assistant).

STARRT-AKI Site Profile

Guy's & St. Thomas' NHS Foundation Trust (London, United Kingdom)

GSFT is located in the heart of London – opposite Big Ben and the Houses of Parliament. The hospital is a large teaching hospital with over 800 beds in total and 53 Critical Care beds with a strong research team. The STARRT-AKI study has great support by the nursing and medical team in the ICU, led by Marlies Ostermann (CI), Duncan Wyncoll, Andy Slack and Luigi Camporota. They have recruited 21 patients so far!



From left to right: Andrea Kelly (RN), Rosaria Lim (RN), Aneta Bociek (RN), Sara Campos (RN); Shuanghong Zhou (Research Coordinator)

Frequently Asked Questions (FAQs)

- 1. If the study coordinator is unable to secure consent within the required 12 hours for a fully eligible patient, can the patient be re-screened when consent is more feasible?**

No, the patient cannot be re-screened for the study if the patient was already considered Fully Eligible but consent could not be obtained within 12 hours. The one exception to this is if the patient had a previous episode of AKI, fully recovered with no dialysis, and then had another episode of AKI while in ICU.
- 2. For the assessment of inclusion criteria 4.iii. [urine output (<6.0 mL/kg) over the preceding 12 hours], from what time point should the 'preceding 12 hours' be determined?**

The preceding 12 hours should be determined from the current time of screening. Further, for the weight, the first recorded weight in hospital should be used. Thus, in order to fulfill this criterion, the patient must be in the ICU for a minimum of 12 hours for the requisite urine output data to be available.
- 3. If a patient is discharged from ICU before day 14 post-randomization and experiences an AE/SAE after the ICU discharge, does this event need to be recorded in the database?**

No, AE/SAEs are only collected from Randomization/Day 0 to Day 14 AND while the patient is in ICU.
- 4. Until what date should we report deaths on the database?**

The death form should be completed if the patient dies within the first 90 days post-randomization (Day 0 to Day 90). After day 90, the patient is considered to have completed the study and all further data will be collected via data linkage (as applicable).

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).

Site Payments

The next payment round will occur in May 2018. Reports will be run on May 14, 2018.

Study Contacts

Coordinating Centre		Principal Investigators	
<p>Nikita Chavda, Project Lead Email: ChavdaN@smh.ca Phone: 416-864-6060 ext. 7893</p>	<p>Jessica Marchese, Project Assistant Email: MarcheseJ@smh.ca Phone: 416-864-6060 ext. 7856</p>	<p>Ron Wald Principal Investigator Email: WaldR@smh.ca Office: 416-867-3703 Cell: 416-258-6540</p>	<p>Sean Bagshaw Principal Investigator Email: Bagshaw@ualberta.ca Office: 780-492-3817 Cell: 780-722-9756</p>