

STARTRAKI

Newsletter Issue 7: December 2017

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



Inside This Issue



- 1 A Message from Ron and Sean
- 2 The World of STARTRAKI
- 2 Cumulative Enrolment Graph
- 3 Recruitment Status
- 3 Announcements
- 3 Study Overview and Updates
- 4, 5 Pictures, Site Visits
- 5 Site Profiles
- 6 Investigator Meetings
- 7 Frequently Asked Questions
- 7 Site Reminders
- 7 Study Contacts

A Message from Sean Bagshaw and Ron Wald

Dear STARTRAKI Team Members,

When we reflect on the story of 2017 in the STARTRAKI trial, one might be initially drawn to the steady progress in the trial's recruitment and this is indeed very gratifying for all of us. We can all say with pride that we are well on our way to definitively answering one of the most vexing questions in the field of critical care nephrology. But beyond the numbers and the specific scientific questions of the trial, we have collectively shown that despite limited resources (and yes, we still need more grant funding!) dedicated teams around the world can come together to answer a research question that is deemed to be of universal clinical importance. We are privileged to be working with such fantastic Site Coordinators and Investigators. We especially appreciate the hospitality we have been afforded on our site visits and the time you have all spent on webinars, answering emails and addressing data queries.

Of course, none of this would be possible without amazing staff at our coordinating centre in Toronto. Nikita Chavda and Jessica Marchese are the glue that holds this trial together and they are further supported by the leadership of the Applied Health Research Centre, Judi Hall and Dr. Peter Juni who have made a tremendous investment in STARTRAKI. Our regional leaders have also been amazing with special "shout-outs" going to Erika Dempsey, Nam Nath Kumar, Jade Newman and Amanda Wang at The George Institute in Sydney, AU, Raulle Sol Cruz in Wellington, NZ, Qin Wang in Beijing and Isabelle Hoffmann and Aline Dechanet in Paris. We are deeply indebted to the hard work and thoughtful advice provided by our Data Safety Monitoring Board, Chaired by Prof Kathy Rowan.

On behalf of the Steering Committee, we would like to wish you and your families our warmest wishes for the holiday season. May 2018 be a year of health, success and fulfillment for all of us.

With warmest regards,
Sean and Ron

Chers membres de l'équipe STARTRAKI,

Lorsque nous pensons au progrès de STARTRAKI pendant l'année 2017, on peut être d'abord impressionné par le recrutement robuste et cela est très gratifiant pour nous tous. Nous pouvons dire avec fierté que nous sommes "en route" vers une réponse définitive à l'une des questions les plus importantes dans le domaine de la néphrologie en soins intensifs. Mais au-delà des chiffres et les questions scientifiques spécifiques de l'essai, nous avons montré collectivement que malgré les ressources limitées (et oui, nous avons encore besoin des subventions supplémentaires!), des équipes dédiées à travers le monde peuvent se réunir pour répondre à une question de recherche qui a une importance universelle. De plus, on a le privilège de travailler avec des coordinateurs et enquêteurs fantastiques. Nous apprécions particulièrement l'hospitalité qui nous a été accordée lors de nos visites sur site et le temps que vous avez passé à participer à des webinaires, à répondre à des courriels et à répondre à des demandes de données.

Bien sûr, rien de tout cela ne serait possible sans le personnel extraordinaire dans notre centre de coordination à Toronto. Nikita Chavda et Jessica Marchese sont la colle de cet essai et elles sont soutenues par le leadership du Centre de recherche appliquée en santé, Judi Hall et Peter Juni, qui ont fait un investissement considérable dans STARTRAKI. Nos dirigeants régionaux ont également été extraordinaires et nous aimerions reconnaître le travail de Erika Dempsey, Nam Nath Kumar, Jade Newman et Amanda Wang au George Institute de Sydney, Raulle Sol Cruz à Wellington, NZ, Qin Wang à Pékin et Isabelle Hoffmann et Aline Dechanet à Paris. Nous sommes profondément reconnaissants pour les conseils fournis par notre Data Safety Monitoring Board, présidé par Prof. Kathy Rowan.

Au nom du comité organisateur de STARTRAKI, nous aimerions vous souhaiter, ainsi qu'à vos familles, nos meilleurs vœux pour la période des fêtes. On espère que 2018 sera une année de santé et de réussite pour nous tous.

Amicalement,
Sean et Ron

Follow STARTRAKI on Twitter!



STARTRAKI is on Twitter!
Follow us on Twitter @STARTRAKI.

Visit Our Website



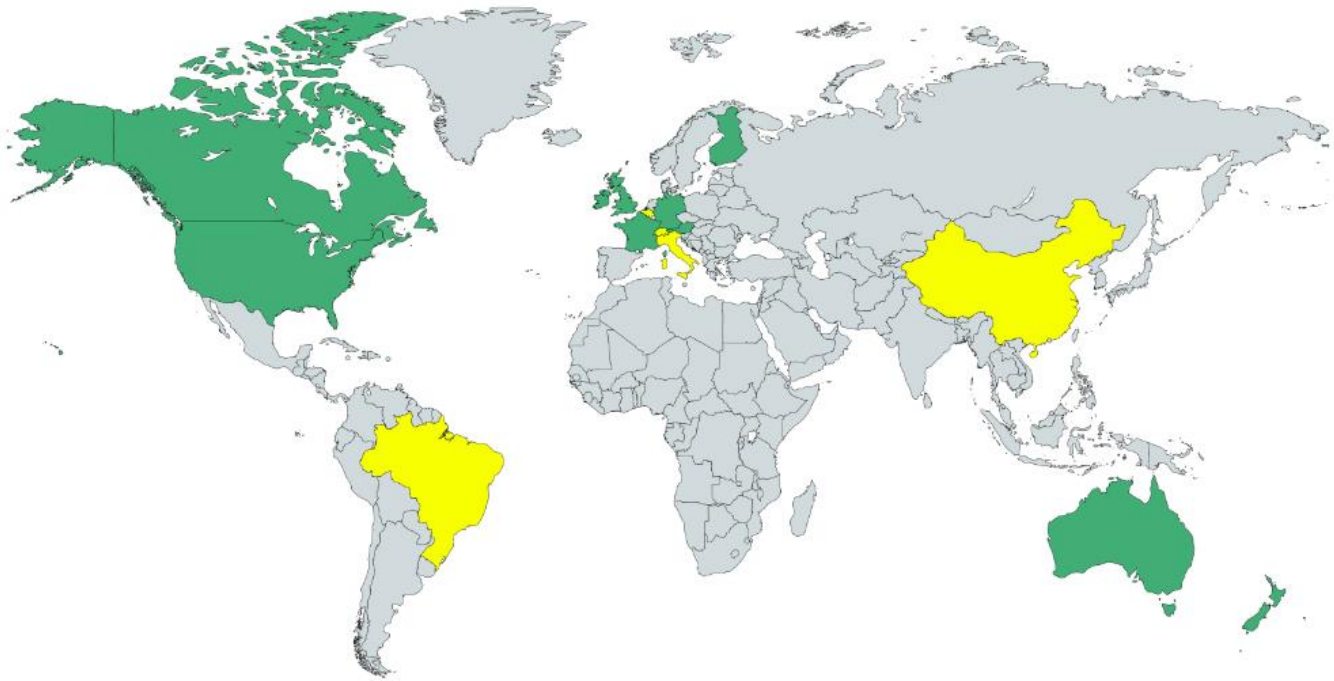
Visit our website [here](#) for the latest updates on the study and for access to study documents.

QxCalculate



Investigators and CRCs 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 STARTRAKI.

The World of STARRT-AKI



Active STARRT-AKI countries

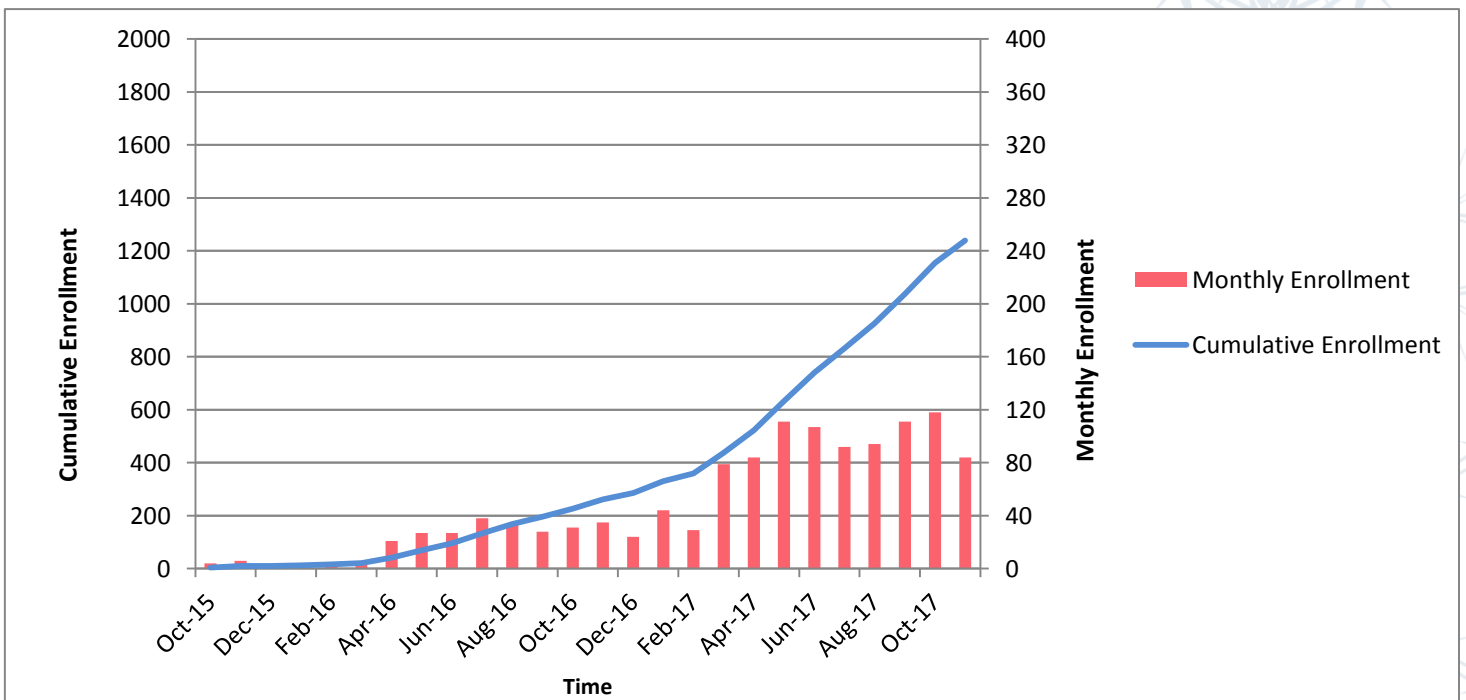
- Canada: 40 active sites; 470 subjects
- France: 29 active sites; 540 subjects
- Australia: 14 active sites ; 179 subjects
- UK: 1 active site; 9 subjects
- Ireland: 1 active site; 3 subjects

- US: 2 active sites; 16 subjects
- Germany: 1 active site; 11 subjects
- New Zealand: 4 active site; 65 subjects
- Austria: 2 sites; 6 subjects
- Finland: 3 active sites; 29 subjects

Soon to Join STARRT-AKI

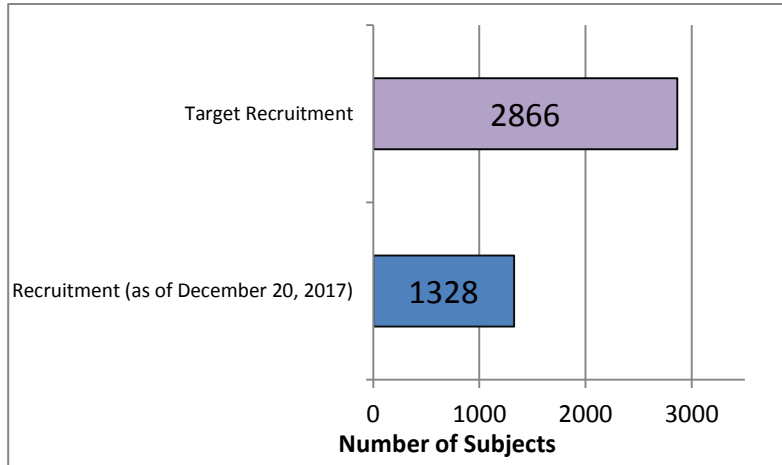
- Switzerland
- Belgium
- China
- Italy
- Brazil

Cumulative Enrollment as of December 20, 2017



Recruitment Status

As of December 20th, 2017, we have randomized a combined **1328** subjects. Thank you to all the sites for your dedication and hard work!



Announcements

Manual of Operations Update

We will be revising the Manual of Operations in the New Year to aid with a more efficient data collection! The changes will be reflected in the collection of Adverse Events and SAEs, providing a more straight-forward and simple approach to recording this data.

1st Interim Analysis

Our first interim analysis has occurred and will be reviewed by our DSMB members in early January 2018, looking at the first 25% of our STARRT-AKI patient population. We would like to thank all the sites for their diligent data entry and hard work!

Awards

Congratulations to Nikita Chavda, Project Manager at the AHRC, for receiving the Unsung Hero Award at St. Michael's Hospital! Nikita has been recognized during Research Month as someone who has gone above and beyond in her role at the AHRC.

Study Overview and Updates

Welcome to **Hawke's Bay Hospital** in New Zealand which is our newest site activated in the month of October!

Recent site activations:

- *Australia and New Zealand:* St. Vincent's Hospital (Sydney), Flinders Medical Centre (Bedford Park), Royal North Shore Hospital (Sydney)
- *Austria:* Medical University Graz (Graz)
- *Canada:* Trillium Health Partners - Mississauga Hospital and Credit Valley Hospital (Toronto, ON)

Upcoming site activations:

- *Australia:* The Northern Hospital (Melbourne), Concord Hospital (Sydney)
- *Belgium:* Ghent University Hospital (Ghent)
- *Brazil:* Hospital de Clínicas de Porto Alegre- Rio grande do Sul (Porto Alegre)
- *Canada:* Health Sciences Centre (Winnipeg, MB)
- *China:* Beijing Friendship Hospital (Beijing), Zhongda Hospital Southeast University (Nanjing), Peking Union Medical College Hospital (Beijing), The First Hospital of Jilin University (Changchun), Guizhou Provincial People's Hospital (Guiyang), The First Affiliated Hospital of Xiamen University (Xiamen), Xiangya Hospital Central South University (Changsha), Shandong Provincial Hospital (Jinan), Zhongnan Hospital of Wuhan University (Wuhan), The First Affiliated Hospital of Xi'an Jiaotong University (Xi'an), Henan Provincial People's Hospital (Zhengzhou), Renmin Hospital of Wuhan University (Wuhan)
- *Germany:* Klinikum Coburg (Coburg)
- *Italy:* San Raffaele Hospital (Milan)
- *New Zealand:* Rotorua Hospital (Rotorua)
- *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)
- *Switzerland:* Centre Hospitalier Universitaire Vaudois, CHUV (Lausanne)
- *USA:* University of Florida (Gainesville), University of Kentucky (Lexington), Rhode Island Hospital and The Miriam Hospital (Providence)

**Sean Bagshaw Visits
The Applied Health Research Centre
October 3, 2017**



Pictured from left to right: Jessica Marchese, Sean Bagshaw, Nikita Chavda and Ron Wald

**Sean Bagshaw Visits Toronto...again!
December 12, 2017**



Pictured from left to right: Jessica Marchese, Nikita Chavda, Ron Wald and Sean Bagshaw

**STARRT-AKI Investigator Meeting at the University of Kentucky
November 27, 2017**



Pictured from left to right:

Juan Carlos Aycinena (Co-Investigator), Javier Neyra (Principal Investigator), Robert Dorfman (ICU Research Nurse), Madona Elias (Research Coordinator) and Victor Ortiz-Soriano (Research Assistant).

STARRT-AKI Investigator Meeting in Beijing, China on August 23, 2017



STARRT-AKI China team hosting Sean Bagshaw

Meet our second highest recruiting site!



Site Profile CHU Dijon Bourgogne (Dijon, France)

Pictured from left to right:

Dr. Audrey Large, Dr. Auguste Dargent, Dr. Andreu Pascal (Investigator), N'Guyen-Soenen (intern), Kévin et Alexandre (students), Dr. Dransart-Ray, Prof. Dr. Sébastien Prin, Prof. Jean-Pierre Quenot (Principal Investigator)

Standing:

Prof. Pierre-Emmanuel Charles

Le service de Médecine Intensive- Réanimation est composé de 15 lits accueillant environ 1,000 patients/an dont 95% de patients médicaux. Les 2 principaux domaines de recherche portés par le service sont : les aspects éthiques concernant l'anticipation des prises de décision en situation complexe et nouvelles approches dans la prévention, le diagnostic et le traitement du sepsis.

Dijon University hospital ICU is composed of 15 beds and with approximately 1,000 admissions per year, 95 % of which are medical patients. The two main areas of clinical research in this ICU relate to the ethical aspects concerning decision-making in complex situations and new strategies for the prevention, diagnosis and treatment of sepsis.

STARRT-AKI Investigator Meetings

Hamilton, Ontario November 14, 2017



**Featuring Hamilton General,
St. Joseph's Healthcare and
Juravinski Hospital**

Pictured from left to right: Jessica Marchese, Nikita Chavda, Ron Wald, Mark Soth (St. Joseph's), Tina Millen (Juravinski Hospital), France Clarke (St. Joseph's), Alex Sabev (Hamilton General) and Bram Rochweg (Juravinski Hospital)

Montreal, Quebec November 21, 2017



**Featuring McGill University
Health Centre (MUHC) and
Centre Hospitalier de
l'Université de Montréal
(CHUM)**

Pictured from left to right: Francois Cailhier (CHUM), Ron Wald, Ahsan Alam (MUHC), Ali Ghamraoui (CHUM), Sheldon Magder (MUHC), Josie Campisi (MUHC), Han Yao (MUHC)

Frequently Asked Questions (FAQs)

1. **A patient was deemed provisionally eligible for the trial a few weeks ago but was not enrolled; he was later discharged from ICU and he recovered kidney function and did not end up requiring dialysis. The same patient is now readmitted to the ICU with a new episode of AKI. If the patient remains in the meets all eligibility criteria, can he be enrolled?**

Patients with recurrent AKI are eligible for the trial. In this case, we are dealing with a new and distinct episode of AKI and since he was not enrolled during his previous episode of AKI (irrespective of the reason), each new episode of AKI should prompt re-screening and re-evaluation of eligibility.

2. **For the Day 28 Resource Utilization Form, what is the time frame for data collection?**

Data collection for the day 28 resource utilization begins from randomization up to and including day 28. This will also include any re-admissions to the ICU/hospital that may have occurred between randomization and day 28.

3. **In regards to the Hospital Re-Admission question on the Day 90 Outcome Data form (was patient re-admitted to hospital between Day 29 and Day 90?), if a patient was still admitted past Day 29, but was discharged prior to Day 90, how should we answer the hospital re-admission at Day 90 question?**

If the patient was discharged between day 29 and day 90 and was not readmitted to the hospital then the response to this question would be "No". If the patient was readmitted to hospital between day 29 and day 90, please choose "Yes" and complete the Hospital Re-Admissions form.

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

This is a reminder to all the sites that the next payments round will occur in the early New Year. Reports will be run on February 12, 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 Email: WaldR@smh.ca Office: 416-867-3703 Cell: 416-258-6540</p>	<p>Sean Bagshaw Email: Bagshaw@ualberta.ca Office: 780-492-3817 Cell: 780-722-9756</p>