



STARTRT AKI

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May 22, 2019

A message from Ron and Sean

Dear STARTRT-AKI Team Members,

We are excited to share that our team continues to grow with new sites having been recently activated in the United Kingdom and Brazil. We are now at 164 sites across 15 countries – truly an inspiring network committed to generating new knowledge on the vexing dilemma of when to ideally start RRT among critically ill patients with AKI!

We have just completed our third interim analysis! As part of interim analysis and data review, we sought the Data Safety Monitoring Board's perspective on extending recruitment to 3,000 from our original intended 2,866 to account for a slightly higher number of patients who were lost to follow-up, withdrew consent or were adjudicated as being ineligible. We are happy to share that the Board has recommended that we continue the trial to completion and have agreed to the extended recruitment. We are grateful to the Data Safety Monitoring Board members for their time and expertise.

With that – we are excited to report that we are nearing the final stretches of enrollment with more than 2,800 patients randomized to date and anticipate achieving our target during the summer.

As always, we are tremendously honored and privileged to work with an enormous and dedicated team! Thank you for your continued support of the STARTRT-AKI trial. We are nearing the finish line!

Sincerely,

Ron and Sean

Un message du Ron et Sean

Chers membres de l'équipe STARTRT-AKI,

Nous sommes heureux de dire que notre équipe continue de se développer, de nouveaux sites ayant été récemment activés au Royaume-Uni et au Brésil. Nous sommes maintenant sur 164 sites répartis dans 15 pays - un véritable réseau inspirant, voué à générer de nouvelles connaissances sur le dilemme de savoir quand commencer idéalement la TRR chez des patients avec l'insuffisance rénale aiguë.

Nous venons de terminer notre troisième analyse intermédiaire! Dans le cadre de l'analyse intermédiaire et de l'examen des données, nous avons cherché à connaître le point de vue du DSMB sur l'extension du recrutement prévu à 2866 à 3 000, afin de prendre en compte un nombre légèrement plus élevé de patients perdus de suivi, ayant perdu leur consentement ou jugés inéligibles. Nous sommes heureux de dire que le DSMB a recommandé de poursuivre l'essai jusqu'à son terme et a accepté de prolonger le recrutement. Nous sommes reconnaissants aux membres du DSMB pour leurs temps et expertise.

Avec cela - nous sommes ravis d'annoncer que nous approchons de la dernière étape du recrutement avec plus de 2 800 patients randomisés à ce jour et nous prévoyons d'atteindre notre objectif durant l'été.

Comme toujours, nous sommes extrêmement honorés et privilégiés de travailler avec une équipe énorme et dévouée! Merci pour votre soutien continu à l'essai STARTRT-AKI. Nous approchons de la ligne d'arrivée!


Cordialement,

Ron et Sean

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 Follow STARTRT-AKI on Twitter [@STARTRAKI](https://twitter.com/STARTRAKI)

 Visit our website [here](#) for study related documents and updates

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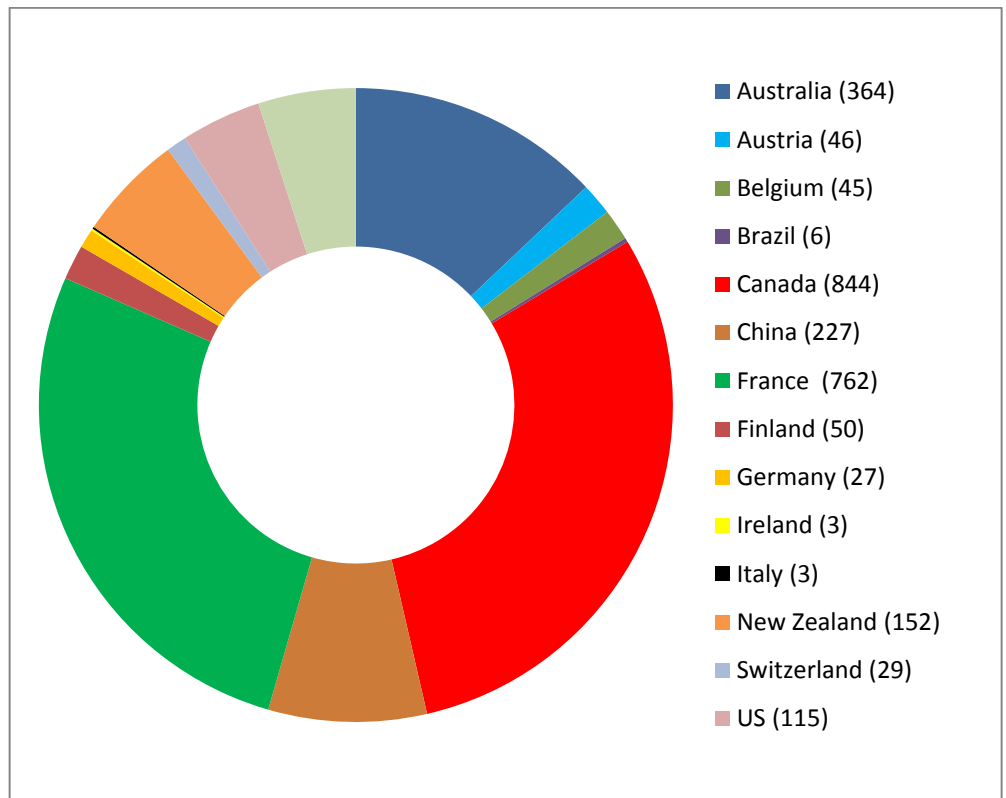
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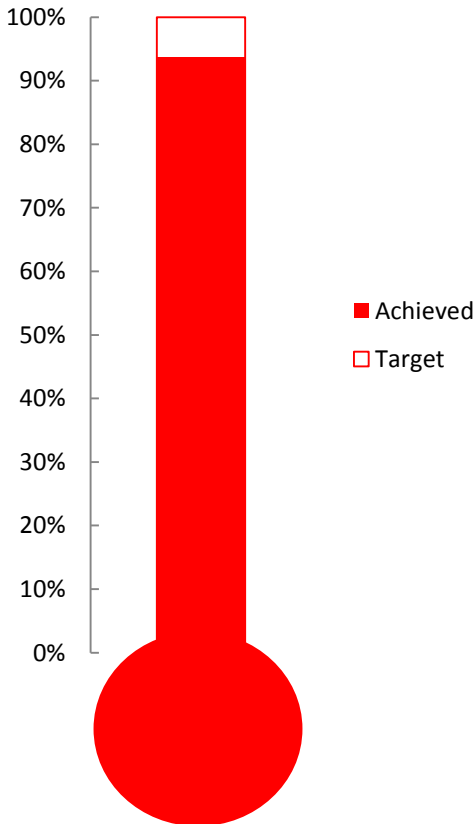
Recruitment Across the Globe

Did you know?

The first patient in STARRT-AKI study was recruited on October 13, 2015 at Austin Hospital in Melbourne!



As of May 22, 2019, we have recruited 2,813 patients!



Welcome to our newest sites!

Warm welcome to **Royal Surrey County Hospital, Royal Brompton and Harefield NHS Trust, Cardiff and Vale University Local Health Board, Monklands Hospital, Lincoln County Hospital, Sheffield Northern General Hospital, and Barnsley Hospital** (all sites located in UK!). We look forward to your first recruitment!

Here are some more sites that we hope will the study soon!

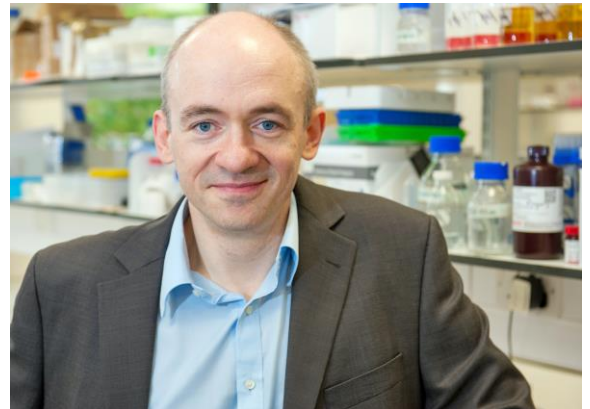
- **Belgium:** ZNA Hospital Antwerp
- **United Kingdom:** Queen Elizabeth Hospital (Birmingham); Chelsea and Westminster NHS Foundation Trust ; Barking, Havering, and Redbridge University Hospital
- **United States:** University of California in Los Angeles

Ron and the STARRT-AKI team at The George Institute in Melbourne!



Pictured from left to right: Ron Wald, Cherub Wayne, Bridie Vaughan, Yachna Mehta, Martin Gallagher, Erika Dempsey, Amanda Wang

Congratulations to Danny McAuley on being appointed the Director of the Efficacy and Mechanism Evaluation Programme of the UK Medical Research Council (MRC) and the National Institute for Health Research (NIHR)



Dr. Neill Adhikari with the STARRT-AKI team at Hospital de Clinicas de Porto Alegre in Brazil!



Pictured from left to right: Dr. Neill Adhikari, Bianca Chiella, Lucia Fendt, Dr. Fernando Thome

Welcome Sydney!



Please join us in welcoming Sydney Currier to the STARRT-AKI team! Sydney is taking over the role of Clinical Study Assistant II at AHRC, as Jessica has moved on to a Clinical Research Specialist role. Congratulations Jess!

Sydney will be working on remote monitoring for STARRT-AKI study, and she will be in touch with each site individually for any outstanding monitoring documents or issues as she transitions into her new role.

Site Reminders

Database Queries

You may have received open query reports from Joyce at the end of April 2019. The deadline to address any open queries for patients randomized until December 31, 2018 has passed on May 13, 2019. Kindly address those queries if you haven't already done so.

Data Entry

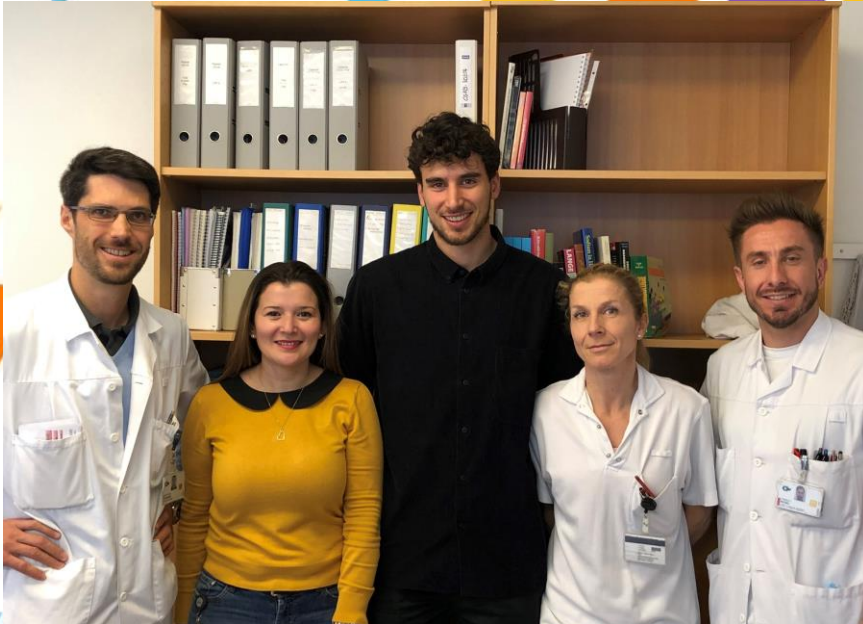
You may notice open queries for missing data on applicable forms for patients randomized until March 31, 2019. Kindly enter data into any forms that have open queries for missing data. Joyce will also be in touch with each site individually toward the end of this month, and will provide the query report along with a deadline date to enter the missing data.

Lost to follow up patients

For patients that are lost to follow up, at minimum we would like to have their vital status at day 90. Some of the alternate ways of obtaining this data if you are unable to contact the patient directly would be to call the patient's family, check national death registries, or check obituaries. Day 90 vital status is the primary outcome of this trial, as such obtaining this data is very important, and we ask that you look into all sources possible to obtain this data.

THANK YOU FOR YOUR CONTRIBUTION!

Centre Hospitalier Universitaire Vaudois (CHUV), Switzerland



Activated in July 2018, CHUV was the first site in Switzerland to join STARRT-AKI. They have recruited 26 patients into the study so far, and are continuing their efforts to recruit more patients. Thank you, team CHUV, for your contributions!

Pictured from left to right:
Dr. Antoine Schneider, Samia Abed Maillard, Dr. Marco Altarelli, Madeleine Schnorf, Dr Michel Thibault.

Ghent University Hospital, Belgium



Ghent University Hospital in Belgium is currently our only active site in this country. They were activated in January 2018, and have recruited a solid 45 patients so far! Kudos to the team!

Pictured from left to right:
Luc De Crop, Prof. Eric Hoste, Daisy Vermeiren, Stephanie Bracke

Helsinki University Central Hospital, Finland



Helsinki University Central Hospital in Finland has been a part of STARRT-AKI study since February 2016, and they are among the first few sites that were activated for recruitment in the study! They have recruited 30 patients into the study to date. Thank you, team Helsinki, for your continuous support of the study!

Pictured from left to right:

Elina Lappi, Suvi Vaara, Prof. Markus Skrifvars, Prof. Ville Pettila, Leena Pettila, Sari Sutinen