



# STARTRT AKI

STandard versus Accelerated initiation of Renal  
Replacement Therapy in Acute Kidney Injury

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Update from Ongoing and Late Breaking Trials

Friday, March 9, 2018 ~ 11:00 – 12:30

AKI & CRRT 2018, San Diego, California



The Intensive Connection



St. Michael's

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Inspiring Science.



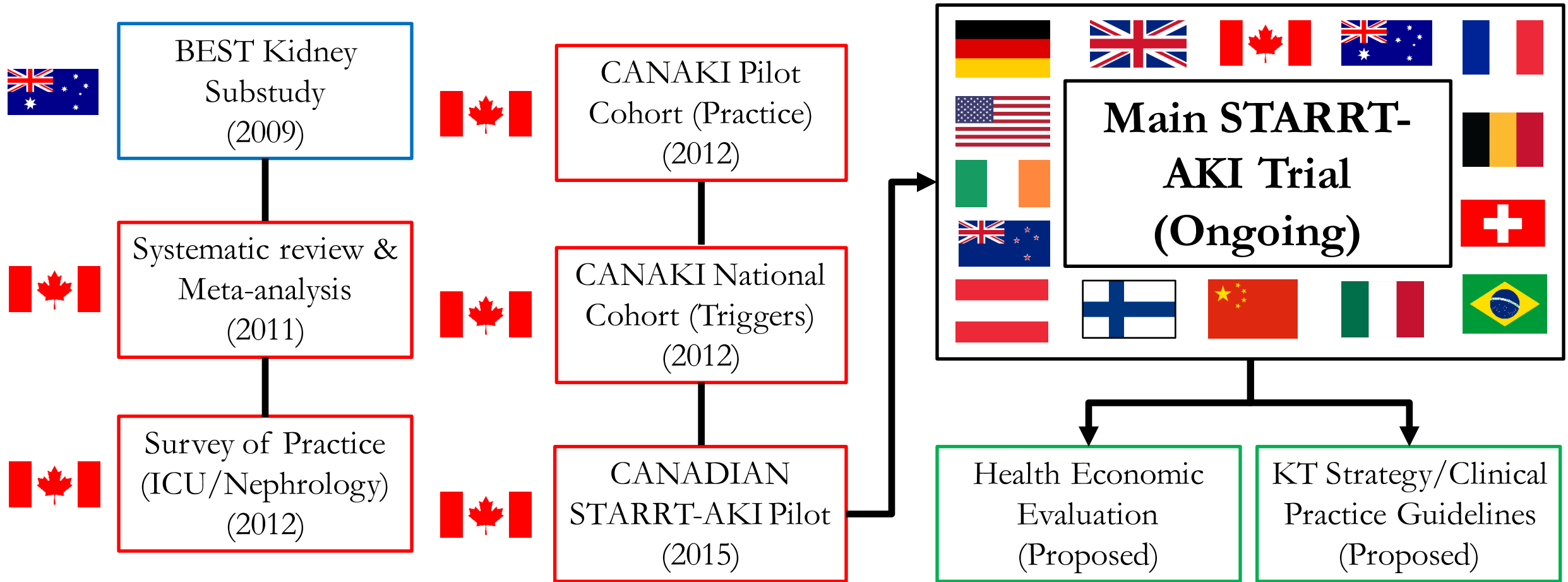
<https://www.ualberta.ca/critical-care/research/current-research/startrtaki>

**The research question STARRT-AKI  
proposes to answer is:**

**Does accelerated (or early) initiation of  
RRT in critically ill patients with AKI  
reduce 90-day all-cause mortality and  
non-recovery of kidney function?**



# STARRT-AKI PROGRAM



- Multi-centre, open-label, randomized controlled trial of accelerated vs. conservative strategies for initiation of RRT in 2,866 critically ill patients with severe AKI

*ClinicalTrials.gov Identifier: NCT02568722*



# KDIGO Stage 2 AKI + no urgent indication + equipoise

Concealed Random Block Allocation Stratified by Center

## Accelerated RRT initiation

Start RRT no more than 12 hr  
after becoming eligible

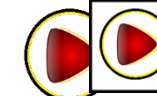
All aspects of prescribed RRT (i.e.,  
modality, dose, anticoagulation) will  
follow current best practice  
guidelines and local standards of care

## Standard RRT initiation

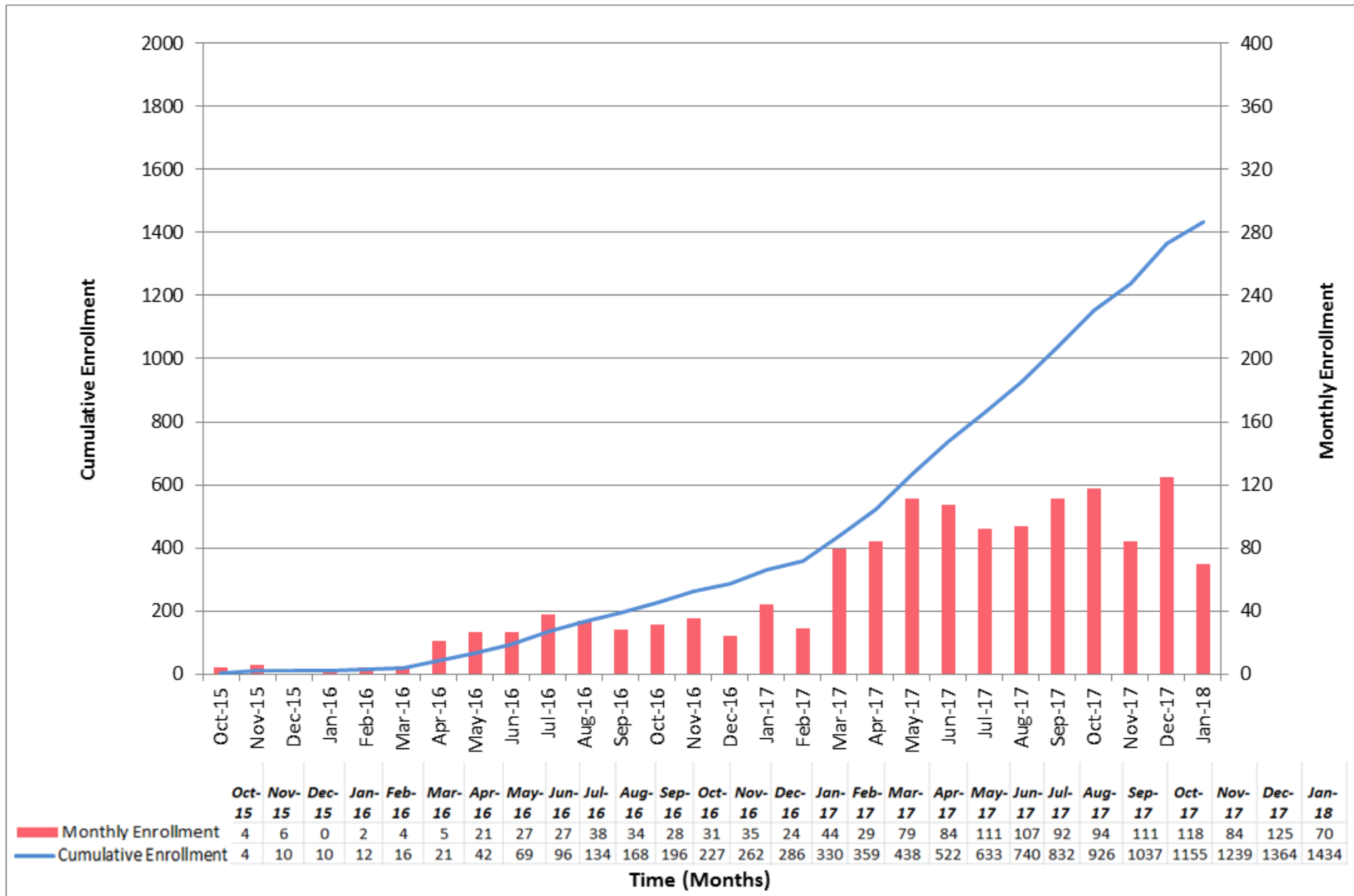
RRT permitted upon  $\geq 1$  of following:

$K \geq 6.0$  mmol/L  
 $\text{pH} \leq 7.20$  or  $\text{HCO}_3 \leq 12$  mmol/L  
 $\text{PaO}_2/\text{FiO}_2 \leq 200$  or perception  
of clinically significant FO  
Persistent AKI for  $> 72$  hr

RRT continued in both arms until death, withdrawal of  
care or evidence of kidney recovery



- **Active Sites**: **110** (Canada, Australia, New Zealand, Finland, Ireland, France, Germany, Austria, England (UK), USA, Belgium)
- **Randomized**: **1499** (52.3%) (weekly enrollment ~ 15-25)



Recruitment Rate	STARRT-AKI Completion
120 patients/month	January 2019
100 patients/month	March 2019
80 patients/month	July 2019
60 patients/month	January 2020
40 patients/month	January 2022
20 patients/month	Possibly not in my lifetime!



- **Funding/Support:**

- CIHR (2) (Operating; Industry-Partnered)
- NHMRC (Project Grant - 2016)
- HRCNZ (Project Grant - 2017)
- NIHS Portfolio application (approved)
- CIHR (Project Grant - 2018)

- **Pending Funding Applications:**

- NIHR HTA grant (Marlies Ostermann)



# STARRT-AKI Team

Site Name	Site PI(s)	Site Coordinator(s)	Site Status
<b>CANADA</b>			
University of Alberta Hospital	Sean Bagshaw	Nadia Baig	Active
Grey Nuns Community Hospital	Shelley Duggan	Jennifer Barchard	Active
Mazankowski Alberta Heart Institute	Sean Bagshaw	Nadia Baig	Active
Misericordia Community Hospital	Erika MacIntyre	Robin Scheelar	Active
Red Deer Regional Hospital	Michael Russell	Gillian Brown	Active
Sturgeon Community Hospital	Gabriel Suen	Aysha Shami	Active
Foothills Hospital	Thomas Stelfox	Joshua Booth	Active
Peter Lougheed Centre	Daniel Niven	Joshua Booth	Active
Royal Alexandra Hospital	Jim Kutsogiannis	Patrica Thompson	Active
Fraser Health - Surrey Memorial Hospital	Greg Haljan	Christopher Condin	Active
St. Paul's Hospital	Peter Dodek	Victoria Alcuaz	Active
Victoria General Hospital	Gordon Wood	Fiona Auld	Active
Royal Jubilee Hospital	Gordon Wood	Fiona Auld	Active
Lakeridge Health	Randy Wax	Kelly Fusco	Active
Hamilton General	Richard Whitlock	Thais Creary	Active
Health Sciences North	John Harmon	Nicole Haslam Sarah Charette	Active
Juravinski Hospital	Bram Rochweg / Timothy Karachi	Tina Millen	Active
Kingston General Hospital	John Muscedere	Miranda Hunt	Active
LHSC – University Hospital	Matthew Weir	Tracey Bentall	Active
LHSC – Victoria Hospital	Ian Ball	Eileen Campbell	Active
Mount Sinai Hospital	Stephen Lapinsky	Sumesh Shah	Active
St. Joseph's Healthcare	Mark Soth	France Clarke	Active

St. Michael's Hospital	Ron Wald	Orla Smith	Active
Sunnybrook Health Sciences Centre	Neil Adhikari	Nicole Marinoff	Active
The Ottawa Hospital - Civic Campus	Lauralyn McIntyre	Rebecca Porteous / Irene Watpool	Active
The Ottawa Hospital - General Campus	Lauralyn McIntyre	Rebecca Porteous / Irene Watpool	Active
Toronto Western Hospital - UHN	Elizabeth Wilcox		Active
Centre Hospitalier Universitaire de Sherbrooke (CHUS)	Francois Lamontagne	Elaine Carbonneau	Active
CHU de Québec (CHUQ) - Université Laval	Alexis Turgeon	Marie-Claude Tremblay	Active
CHUM - Hopital Saint-Luc	Francois Cailhier	Ali Ghamraoui	Active
CHUM - Hotel-Dieu de Montreal	Francois Cailhier	Ali Ghamraoui	Active
CHUM - Notre Dame Hospital	Francois Cailhier	Ali Ghamraoui	Active
CIUSSS MCQ	Ying Tung Sia	Patricia Alarie	Active
Hopital Maisonneuve-Rosemont	Jean-Philippe Lafrance	Emilie Rene	Active
Institut Universitaire de cardiologie et de pneumologie de Quebec (IUCPQ)	Francois Lellouche	Patricia Lizotte	Active
McGill University Health Centre	Sheldon Magder	Josie Campizi	Active
Regina Qu'Appelle Health Authority	Bhanu Prasad	Shelley Giebel / Denyse Vanchu	Active
Toronto General Hospital - UHN	Margaret Herridge		On hold
Memorial University of Newfoundland	Brandon Barrett	Anne Marie Whelan	On hold
Health Sciences Centre	Claudio Rigatto	Anna Glybina	Activation process in progress
Trillium Health Partners - Credit Valley Hospital	Vincent Ki	Martin Romano	Active
Trillium Health Partners - Mississauga Hospital	Vincent Ki	Martin Romano	Active
<b>USA</b>			
Mayo Clinic	Kianoush Kashani	Suanne Weist	Active
University of Alabama at Birmingham	Ashita Tolwani	Anita (Laura) Latta	Active
University of Florida	Azra Bihorac	Sandhya Cheda / Melissa Dawn	Activation process in progress
University of Kentucky	Javier Lozano	Madona Elias	Activation process in progress

Rhode Island Authority	Sairah Sharif	Ann O'Maara	Activation process in progress
Baylor University Medical Center	Harold Szerlip	Dianna Robinson	Activation process in progress
<b>AUS/NZ</b>			
Austin Hospital	Rinaldo Bellomo	Glenn Eastwood	Active
Princess Alexandra Hospital	Peter Kruger	Emma Saylor / Jason Meyer	Active
Western Health (Footscray Hospital)	Dashiell Gantner	Anna Tippett/ Samantha Bates	Active
The Alfred Hospital	Andrew Udy	Phoebe McCracken	Active
Royal Prince Alfred Hospital	David Gattas	Heidi Buhr	Active
Nepean Hospital	Louise Cole	Christina Whitehead	Active
Nambour General Hospital	Victoria Campbell	Jane Brailsford	Active
Geelong Hospital		Allison Bone	Active
Bendigo Hospital	Timothy Chimunda	Julie Smith	Active
Ballarat Hospital	Angus Richardson	Diane Hill	Active
Eastern Hospital (Box Hill and Maroondah Hospital)	Graeme Duke	Deborah Welsh	Active
The Northern Hospital	Angaj Ghosh	Simone Said	Activation process in progress
Flinder Medical Centre	Alpesh Patel / Shailesh Bihari	Elisha Matheson / Kate Schwartz	Activation process in progress
Concord Hospital	Rosalba Cross	Helen Wong	Activation process in progress
Royal North Shore Hospital	Celia Bradford	Anne O'Connor	Active
St. Vincent's Hospital	Priya Nair	Claire Reynolds	Active
Wellington Hospital	Paul Young	Anna Hunt	Active
Auckland City Hospital	Shay McGuinness		Active
Christchurch Hospital		Jan Mehrrens	Active
Auckland Hospital DCCM	Colin McArthur	Lynette Newby	Activation process in progress
Hawke's Bay Hospital			Activation process in progress
<b>EUROPE (FRANCE)</b>			
Hôpital Louis Mourier	Didier Dreyfuss	Emeline Dubief	Active

Centre Hospitalier Départemental La Roche-Sur-Yon	Martin Lefevre		Active
CHU D'Amiens	Julien Maizel	Marie Laurence Lepilliez	Active
Hôpital Pitiè Salpêtrière	Julien Mayaux	Laura Morizot	Active
Hôpital Avicenne	Yves Cohen		Active
Hôpital Edouard Herriot	Laurent Argaud	Sylvie De La Salle	Active
CH De Bourg-en-Bresse – Fleyriat	Remi Bruyere		Active
CHRU de Nîmes - Service de Réanimation	Saber Barbar	Audrey Ambert / Solenne Villot	Active
CHU De Rouen	Fabienne Tamion	Pauline Enguerrand	Active
CH Sud Francilien	Guillaume Chevrel		Active
CHU Dijon Bourgogne	Jean-Pierre Quenot		Active
CH Le Mans	Nicolas Chudeau	Alain Robert	Active
Hotel Dieu - Service d'Anesthesie	Karim Asehnoune		Active
CH de Béthune Beuvry – Germont et Gauthier	Christophe Vinsonneau	Mélanie Verlay	Active
Hopital G. Montpied	Bertrand Souweine	Mireille Adda / Frederic Ducee	Active
CH de Dieppe	Jean-Philippe Rigaud		Active
Hôpital Henri Mondor	Nicolas Prost	Sadaoui Thiziri	Active
Hôpital Civil	Ferhat Meziani	Samir Chenaf	Active
CHU de Pointe à Pitre	Bertrand Pons		Active
André Mignot	Benjamin Zuber	Sebastien Cavelot	Active
Centre Hospitalier Dr. Schaffner (Lens)	Christophe Vinsonneau		Active
Hôpital Nord Laennec	Karim Lakhal	Laurence Pacaud	Active
Groupe Hospitalier Carnelle-Portes de l'Oise	Eric Boulet	Mathilde Sampaio	Active
Hotel Dieu – Service de Médicale	Jean Reignier		Active
Hôpital de la Source - CHR d'Orléans	Thierry Boulain	Lucie Muller	Active
CH René DUBOS – Pontoise	Eric Boulet	Nathanael Charrier	Active
CH Lyon Sud – Pierre Benite	Guillaume Thiery		Active

HEGP : Hôpital Européen Georges-Pompidou	Philippe Markowicz		Active
Service de reanimation medicale – Hopital Pitie Salpetriere	Allen Combes		Active
<b>EUROPE (OTHER COUNTRIES)</b>			
<b>AUSTRIA</b>			
Medical University Innsbruck	Michael Joannidis	Klemens Zotter	Active
Medical University Graz	Philipp Eller		Activation process in progress
General Hospital Vienna, ICU	Thomas Staudinger		Activation process in progress
<b>BELGIUM</b>			
Ghent University Hospital	Eric Hoste	Stephanie Bracke	Activation process in progress
Universitair Ziekenhuis Antwerpen			Activation process in progress
St. Luc			Activation process in progress
<b>FINLAND</b>			
Helsinki University Hospital	Ville Pettila	Sari Sutinen / Juuma Eveliina	Active
Tampere University Hospital	Sari Karlsson	Kaisa Malila / Simo Varila	Active
Turku University Hospital	Mikko Jarvisalo	Satu Kentala	Active
<b>GERMANY</b>			
University Hospital Munster	Alex Zarbock	Stephanie Volmering	Active
Klinikum Coburg	Orfeas Liangos		Activation process in progress
<b>IRELAND</b>			
St. Vincent's University Hospital	Alistair Nichol	Ciara Fahey/Kathy Brickel	Active
<b>SCOTLAND</b>			
Queen Elizabeth University Hospital	Malcolm Sim		Activation process in progress
Ayr Hospital	Amadeusz Ziarkowski		Activation process in progress
Golden Jubilee National Hospital	Ben Shelley		Activation process in progress
Aberdeen Royal Infirmary	Jan Jansen		Activation process in progress
Hairmyres Hospital	Jim Ruddy		Activation process in progress
Monklands District General Hospital	Jim Ruddy		Activation process in progress
<b>SWITZERLAND</b>			
Centre Hospitalier Universitaire Vaudois (CHUV)	Antoine Schneider		Activation process in progress

UK			
Guy's and St. Thomas NHS Foundation	Marlies Ostermann	Arbane Gill / Aneta Bociek	Active
ITALY			
San Raffaele Hospital	Giovanni Landoni		Activation process in progress
AOUG Martino	Alberto Noto		Activation process in progress
Ospedale Mauriziano - Torino	Alessandro Bianchi		Activation process in progress
CHINA			
Beijing Friendship Hospital, Capital Medical University	Meili Duan		Activation process in progress
Zhongda Hospital Southeast University	Yi Yang		Activation process in progress
Peking Union Medical College Hospital	Bin Du		Activation process in progress
The First Hospital of Jilin University	Zhong Liu		Activation process in progress
Guizhou Provincial People's Hospital	Xianqing Shi		Activation process in progress
The First Affiliated Hospital of Xiamen University	Minwei Zhang		Activation process in progress
Xiangya Hospital Central South University	Shuangping Zhao		Activation process in progress
Shandong Provincial Hospital	Chunting Wang		Activation process in progress
Zhongnan Hospital of Wuhan University	Zhiyong Peng		Activation process in progress
The First Affiliated Hospital of Xi'An Jiaotong University	Xue Wang		Activation process in progress
Henan Provincial People's Hospital	Bingyu Qin		Activation process in progress
People's Hospital of Wuhan University			Activation process in progress
BRAZIL			
Hospital de Clínicas de Porto Alegre- Rio grande do Sul	Fernando Thome	Bianca Chiella	Activation process in progress

# Pending Activation

- Austria (2)
- Belgium (3)
- Brazil (5-10)
- China (12)
- England (12)
- Germany (1)
- Italy (3)
- Scotland (5)
- Switzerland (3)
- USA (2)



# DSMC: 1<sup>st</sup> Interim Analysis

- **DSMC:** Kathy Rowan (Chair); Dean Fergusson; Stuart Goldstein; David Harrison; Tim Walsh
- **Safety analysis:** second 600 patients - no concerns for first 600 patients enrollment
- **Interim analysis:** first 716 patients
- **Performed:** Jan 12, 2018

# STARRT-AKI Website

https://www.ualberta.ca/critical-care/research/current-research/starrtaki

- About Us +
- Education +
- Research
  - Royal Alexandra Hospital
  - University of Alberta
  - Current Research
    - CFS Implementation
    - STARRT-AKI**
    - Eligibility and Criteria
    - Interventions
    - Trial Endpoints
    - Documents
    - Newsletters
    - Related Links and Publications
    - Contacts and Locations
    - Peer Reviewed Grants
    - Recent Publications
    - Resources
    - Patient Safety & Quality

## Standard vs. Accelerated Initiation of Renal Replacement Therapy (STARRT-AKI)

### Purpose

The objectives of this trial are to determine whether, in critically ill patients with severe acute kidney injury (AKI), randomization to accelerated initiation of renal replacement therapy (RRT), compared to standard initiation, leads to:

1. Improved survival (primary outcome); and
2. Recovery of kidney function (principal secondary outcome), defined as independence from RRT at 90 days

### Detailed Description

Acute kidney injury (AKI) is a common and devastating complication of critical illness. Once AKI is established, treatment is largely supportive and no intervention has been found to restore kidney function or improve overall survival. Renal replacement therapy (RRT), usually in the form of hemodialysis, is frequently needed to manage patients with severe AKI. Such patients have an in-hospital mortality that consistently exceeds 50% with delays in RRT initiation implicated as a possible contributor. A recent meta-analysis suggested that earlier initiation of RRT may improve survival, but this is based on data derived overwhelmingly from observational studies. The investigators recently completed a multi-centre randomized controlled pilot trial that confirmed the feasibility of allocating patients to

### Sites Worldwide

39

### Enrollment

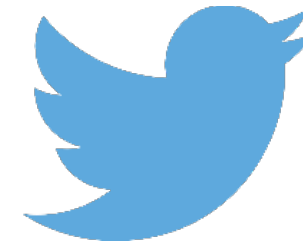
**December 12, 2016**  
Enrollment to date: 272  
Total target enrollment: 2866  
Percentage of target recruitment: 9.5%

### Current enrollment by country:

- Australia: 86
- Canada: 156
- Finland: 7
- Ireland
- New Zealand: 23
- United States

### Upcoming Investigator Meetings

STARRT-AKI Investigator and Start Up



STARRT-AKI

The STARRT-AKI Trial  
@AkiStarrt

A Multi-National RCT of Standard Versus Early Accelerated Renal Replacement Therapy in Critically Ill Patients with Acute Kidney Injury (NCT02568722)

Canada [ualberta.ca/critical-care/...](https://ualberta.ca/critical-care/)

26 FOLLOWING 200 FOLLOWERS

Tweets Media Likes

The STARRT-AKI Trial @AkiStarrt · 1d  
Best enrollment week to date (13 randomized)! Thanks to @AkiStarrt sites for their dedication and effort!@CCCTG\_@ANZICS\_CTG

You Retweeted  
Ron Wald @DrRonWald · 2d

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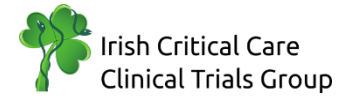


# Acknowledgements

- Funded by:



- Endorsed by:



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Erika Dempsey

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Amanda Wang