



UNIVERSITY OF ALBERTA

Information Sheet and Consent Form

Title of Project: STandard versus Accelerated initiation of Renal Replacement Therapy in Acute Kidney Injury (STARRT-AKI): A Multi-Centre, Randomized, Controlled Trial

Principal Investigator:

Phone Number: XXX-XXX-XXXX

Co-Investigators:

In the case of third party consent, 'you' always refers to the research participant. The pronouns 'you' and 'your' should be read as referring to the participant rather than the parent/guardian/next-of-kin who is signing the consent for the participant.

WHY AM I BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being asked to be in this study because you have injury to your kidneys and are at increased risk for needing dialysis therapy during your stay in the intensive care unit. This study is being performed because we are uncertain about when is the best time to start dialysis therapy in patients with injured kidneys.

Before you make a decision one of the researchers will go over this form with you. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be given a copy of this form for your records.

WHAT IS THE PURPOSE OF THE STUDY?

Acute injury to the kidneys is common in sick patients who are in an intensive care unit. Such kidney injury can have adverse health effects and place patients at increased risk for complications and death. When such injury occurs, many patients may need to have their kidneys supported with dialysis therapy. We are not certain of the best time to start dialysis therapy in patients with injured kidneys.

Prior studies have found that the start of dialysis therapy for sick patients in the intensive care unit may influence patient survival and need for outpatient dialysis therapy. In these studies, the earlier start of dialysis therapy (i.e., accelerated start) allowed for better control of the balance of fluid and electrolytes in the body and prevented complications due to kidney failure, when compared to a more conservative strategy of dialysis therapy (i.e., standard indications to start). However, accelerated start of dialysis therapy may result in some patients receiving it when it may not have been needed.

The purpose of the STARRT-AKI Trial is to assess the best time to start dialysis therapy in sick patients in the intensive care unit who have acute injury to their kidneys and who are at increased risk of a poor outcome.

This study will include 2,866 patients that are admitted to 100 intensive care units across Canada, the United States, Europe and Australia and New Zealand. We plan to enroll 150 patients at the **[[[SITE]]]**.

WHAT WOULD I HAVE TO DO?

If you agree to participate in this study and sign an informed consent, some health information, such as your age and gender will be collected in study data forms. Information about your past medical history, current hospital admission, and treatment will also be recorded. This information will be collected either directly from you or from your health records, including your electronic medical record. The study personnel may need to access your health records up to 1 year after the study is complete to confirm and verify any specific health information directly related to your participation in the study.

As part of the process to determine if you were eligible for this study, we have evaluated how well your kidneys were working. We have done this by looking at the results of your routine blood work that included tests that measure your kidney's function, and assessed the amount of urine your kidneys have been making.

If you are eligible to participate, you will be assigned to one of two treatment groups, by random selection (like flipping a coin):

- One group will receive ***early start of dialysis*** therapy
- The other group will receive ***standard start of dialysis*** therapy, based on the decision of the intensive care physician

If you are allocated to ***early start of dialysis*** therapy, you will have a dialysis catheter placed and have dialysis started within 12 hours of fulfilling eligibility for the study.

If you are allocated to the ***standard start of dialysis*** therapy, you will be followed daily to see if you fulfill any of the standard criteria for start of dialysis, at which time you would be started. Ultimately, the final decision will be made by your physicians, as would be the case if you were not participating in this study. The physicians will use their best judgment to decide when you need to start dialysis.

Regardless of which group you have been assigned to, you will undergo the same procedures. The only difference between the two groups is the time you start receiving dialysis.

While you are enrolled in the study, your vital signs and blood work will be watched closely while you are in the intensive care unit.

As part of the study, you will be asked to have a routine blood and urine test to assess how your kidneys are functioning at approximately 3 months and 1 year after participating in the study. In addition, a member of the research team will contact you by telephone to ask you some questions about your health at approximately 3 months and 1 year after the study. This should take no longer than about 10 minutes. No additional tests, beyond that mentioned above, will be done. This study will not require any added time from you.

If you received dialysis therapy as part of this study, it will be continued until your kidneys have recovered and it is no longer needed. This may occur after you leave the intensive care unit.

WHAT ARE THE RISKS?

Dialysis therapy is commonly used in the intensive care unit to support patients like you whose kidneys are injured and not working. If you are allocated to the early dialysis group, you will have dialysis started as soon as possible after enrollment. The main risk, if you are in the early dialysis arm, is that you will receive dialysis therapy as part of the study, when there is a possibility that your kidneys would recover without it and it would not have been needed. The risks of dialysis therapy itself may include complications related to placing of the dialysis catheter into a large vein. These are uncommon, but can include pain, bleeding, and in rare instances a collapsed lung when placed in a large vein in the neck. There are also risks associated with dialysis therapy that may include changes to your blood pressure and low levels of potassium and phosphate in your blood. These risks are minimized by the close monitoring that all patients started on dialysis therapy routinely receive. If you are allocated to the standard start of dialysis arm, the same risks would apply, however, there is a chance that your kidneys may recover before dialysis is needed and it would not be started.

WILL I BENEFIT IF I TAKE PART?

You may or may not have any direct benefit by taking part in this study. This study is designed to assess which strategy to starting dialysis, early or standard, is most safe and effective.

WILL I BE PAID FOR PARTICIPATING?

You will receive no payment for taking part in this study. There will be no additional costs to you for participating.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

If you become ill or injured as a result of being in this study, you will receive necessary medical treatment, at no additional cost to you. By signing this consent form you are not releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

WILL MY INFORMATION BE KEPT PRIVATE?

During the study we will be collecting health data about you. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your name will be released outside of the study doctor's office or published by the researchers. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your health information is kept private.

The study doctor/study staff may need to look at your personal health records held at the study doctor's office, and/or kept by other health care providers that you may have seen in the past (i.e. your family doctor). Any personal health information that we get from these records will be only what is needed for the study.

During research studies it is important that the data we get is accurate. For this reason your health data, including your name, may be looked at by people from:

- Study personnel at the University of Alberta research team, and/or
- Members of the University of Alberta Research Ethics Board, and/or

- Auditors from the University of Alberta, and/or
- Applicable government regulatory authorities, and/or
- Authorized representatives of the study sponsor
-

Such access will be used only for the purpose of verifying the authenticity and accuracy of the information collected for the study, without violating your confidentiality, to the extent permitted by applicable laws and regulations. By signing this consent form you are giving permission for the study doctor/staff to collect, use and disclose information about you from your personal health records as described above.

After the study is done, we will still need to securely store your health data that was collected as part of the study. In Canada, the law says we have to keep the data stored for 25 years after the end of the study.

If you leave the study, we will not collect new health information about you, but we will need to keep the data that we have already collected.

DO I HAVE TO PARTICIPATE?

Your decision to take part in this study is your choice. . If you decide to be in the study, you can change your mind and stop being in the study at any time, and it will in no way affect the care or treatment that you are entitled to. If the study staff feels that it is in your best interest to withdraw you from the study, they will remove you without your consent. If the study sponsor decides to end the study early, for any reason, you may also be removed from the study without your consent.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

CONTACT INFORMATION:

If you have further questions concerning matters related to this research, please contact:

XX – Site PI – XX: XXX-XXX-XXXX
Research Coordinator: XXX-XXX-XXXX

If you have questions or concerns about your rights as a study participant, you may contact the **Research Ethics Office** of The University of Alberta at **780-492-2615**. This office is independent of the study investigators.



UNIVERSITY OF ALBERTA

Consent Form

Title of Project: STandard versus Accelerated initiation of Renal Replacement Therapy in Acute Kidney Injury (STARRT-AKI): A Multi-Centre, Randomized, Controlled Trial

Principal Investigator: Phone Number: XXX-XXX-XXXX

Co-Investigators:

Table with 2 columns: Question, Yes, No. Contains 8 rows of consent questions.

If so, give his/her name _____

Who explained this study to you? _____

I agree to take part in this study: YES [] NO []

Signature of Research Participant _____

(Printed Name) _____ Date _____

Signature of Witness _____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Person Obtaining Consent _____ Date _____

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH PARTICIPANT