

Alberta Kidney Care – South (AKC-S)

Division of Nephrology Research Group

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Division of Nephrology Research Group

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OVERVIEW OF CLINICAL RESEARCH PROGRAM

Definition of Clinical Research

- Research studies in humans that follow a pre defined protocol
- A protocol is a study plan that a clinical trial is based on
- Designed to answer specific Research questions
- Designed to answer specific Research questions
- Provides details on how the Research questions will be answered
- Provides background and rationale for the study
- Specifies how the data will be collected & analyzed
- The types of people who may participate in the trial (inclusion / exclusion criteria)
- What types of tests & procedures will be done and when
- Any interventions (if applicable) which will be used (e g drugs)
- Duration of the study & overall number of participants that will be involved

Phases of Clinical Trials

Phase I trials:

Small group of people (- 20 - 80)

Experimental drug or treatment tested in humans for the first time

Evaluate the safety, determine safe dosage range, and identify side effects

Phase II trials:

Larger group of people (- 100 - 300)

Experimental drug or treatment tested for the effectiveness in targeted population To further evaluate safety

Phase III trials:

Large group of people (-1,000 - 3,000) Confirm effectiveness, monitor side effects Compare it to commonly used treatments

Gather information that will allow experimental drug or treatment to be used safely

Phase IV trials:

Post marketing studies (using approved drugs/treatments) Provide additional information on long term safety and optimal use

Study Designs

Interventional studies:

Research subjects are assigned to a treatment or intervention

Observational studies:

Research subjects are observed (no treatment/intervention involved)

Trial types

Investigator initiated:

Physicians design the protocol and conduct the study

Industry sponsored:

Pharmaceutical/Biotech or other organizations design the protocol

INDUSTRY SPONSORED RESEARCH PROJECTS

1. VIS649-201 for IgA Nephropathy

Principal Investigator	Clinical Research Trial
Dr. Louis Girard	Sharon Gulewich

2. Pragmatic randomized trial of High Or Standard PHosphAte Targets in End-stage kidney disease

Principal Investigator	Clinical Research Trial
Dr. Louis Girard	Coralea Bignell

INVESTIGATOR INITIATED RESEARCH PROJECTS
1. Sexual function and Activity among Women with ESKD

Principal Investigator	Clinical Research Trial
Dr. Sofia Ahmed	Darlene Sola

2. Incremental Dialysis Mixed-Methods Study

Principal Investigator	Clinical Research Trial
Dr. Sofia Ahmed	Kelsea Drall

3. Serum AMH & Arterial Stiffness in Women with CKD - Sandi Dumanski – MSc project

Principal Investigator	Clinical Research Trial
Dr. Sofia Ahmed	Darlene Sola

4. Precision Medicine for CKD and End-stage Kidney Disease on Hemodialysis

Principal Investigator	Clinical Research Trial
Dr. Justin Chun	Francine Milone

5. Sexual Health and Kidney Disease: An Environmental Scan of the Beliefs, Perceptions, and Priorities of Canadians with Kidney Disease

Principal Investigator	Clinical Research Trial
Dr. Sandi Dumanski	Tessa Woodside (Student)

6. Peer Support in CKD Care

Principal Investigator	Clinical Research Trial
Dr. Meaghan Elliott	Shannan Love

7. Potentially preventable emergency department use in kidney failure

Principal Investigator	Clinical Research Trial
Dr. Meaghan Elliott	Shannan Love

8. A qualitative study on the implementation of PROMs in routine hemodialysis care

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Dr. Meaghan Elliott	Sharon Gulewich

11. Development and pilot study of the early-stage chronic kidney disease self-management (esCKD-SM) survey instrument

Principal Investigator	Clinical Research Trial
Dr. Brenda Hemmelgarn	Sabrina Jassemi

12. Co-designing and testing of a chronic kidney disease patient self-management electronic (eHealth) tool

Principal Investigator	Clinical Research Trial
Dr. Brenda Hemmelgarn	Sabrina Jassemi

13. Prognostic Tools For Cardiovascular and Kidney Events in People with Kidney Disease

Principal Investigator	Clinical Research Trial
Dr. Matt James	Pantea Javaheri

14. Advancing community care and access to follow-up after AKI hospitalization

Principal Investigator	Clinical Research Trial
Dr. Matt James	Coralea Bignell

15. A Randomized Controlled Trial of Urine CXCL10 Chemokine Monitoring Post-Renal Transplant (TMCT-04)

Principal Investigator	Clinical Research Trial
Dr. Ngan Lam	Francine Milone

16. Outcomes of a higher vs. lower hemodialysate magnesium concentration

Principal Investigator	Clinical Research Trial
Dr. Jennifer MacRae	Janice MacKay

17. Cardiac Remodeling Using Magnetic Resonance Technique: A Pilot Study

Principal Investigator	Clinical Research Trial
Dr. Jennifer MacRae	Sharon Gulewich

18. Home Dialysis Program technique failure: a quality improvement initiative

Principal Investigator	Clinical Research Trial
Dr. Jennifer MacRae	

19. Wellness in kidney disease

Principal Investigator	Clinical Research Trial
Dr. Jennifer MacRae	

20. Improving patient transition to dialysis (DTU)

Principal Investigator	Clinical Research Trial
Dr. Jennifer MacRae	Naveen Naz

21. ACHIEVE Study – Can-SOLVE CKD

Principal Investigator	Clinical Research Trial
Dr. Braden Manns	Coralea Bignell

22. Biobank Healthy Volunteer Program

Principal Investigator	Clinical Research Trial
Dr. Braden Manns	Sharon Gulewich

23. Renal Biobank & TARGET KD

Principal Investigator	Clinical Research Trial
Dr. Dan Muruve	Sandra MacKay

24. SPOR- Can-SOLVE CKD - CGNR

Principal Investigator	Clinical Research Trial
Dr. Daniel Muruve	Francine Milone

25. Biobank Healthy Volunteer Program

Principal Investigator	Clinical Research Trial
Dr. Daniel Muruve	Francine Milone

26. Accelerometry in Kidney Transplant Patients

Principal Investigator	Clinical Research Trial
Dr. Stefan Mustata	Kathryn Wytmsa-Fisher

27. Strategies for the management of Atrial Fibrillation in patiEnts receiving Dialysis (SAFE-D)

Principal Investigator	Clinical Research Trial
Dr. Rob Quinn	Francine Milone

28. PD Catheter Registry

Principal Investigator	Clinical Research Trial
Dr. Rob Quinn	Sandra MacKay

29. CVC vs. AVF Study

Principal Investigator	Clinical Research Trial
Dr. Pietro Ravani	Sharon Gulewich
Dr. Rob Quinn	

30. Canadian Kidney Disease Cohort Study (ESRD)

Principal Investigator	Clinical Research Trial
Dr. Cello Tonelli	Charlynn Ursu