1. BACKGROUND

- The average life expectancy on dialysis is only 3 years.
- 40% of dialysis patients will die from heart disease.
- Dialysis causes heart disease due to:
  - Pressure and fluid overload
  - Heart muscle injury and scarring
  - Narrowing of blood vessels to the heart
  - Abnormal heart rhythms leading to sudden cardiac death
  - Effective treatments for heart disease in dialysis are lacking.
  - Aldosterone is a hormone implicated in heart disease related to dialysis.
  - Drugs that block aldosterone are effective in non-dialysis settings.

2. PROJECT GOAL

- To determine if spironolactone reduces cardiovascular morbidity and mortality for patients treated with chronic dialysis.

3. PROJECT TEAM

- Role of patient partners
  - Explore barriers to recruitment and potential solutions:
    - Focus on simplifying study
    - Minimal study visits and data collection
    - Preparing study materials in better ways to maximize impact
  - Emphasize the importance of participant contribution to research.

4. WHAT IS THE STUDY DESIGN?

A) Eligibility Criteria

Inclusion
1. Age ≥ 18
2. Diabetes
3. On either
   - Hemodialysis at least 90 days
   - Peritoneal dialysis >1 exchange/day
4. Provide informed consent

Exclusion
1. Hypokalemia
2. Serum potassium <3.5 mmol/L in 6 weeks prior
3. Serum potassium >5.0 mmol/L during active run-in
4. Current or planned pregnancy or breastfeeding
5. On dialysis ≤90 days
6. Life expectancy <6 months in the opinion of a treating nephrologist
7. History of heart failure in the previous year
8. Scheduled living related donor renal transplant

B) Study design

- Open label active run-in period identification + exclusion
- High blood levels of potassium ≥ 3.0 mmol/L and ≥80% adherence
- Double blind post-randomisation spironolactone 25mg orally daily up to placebo follow-up every 6 months during dialysis.

5. ACHIEVEMENTS/LESSONS LEARNED

- N=at least 2750
- One of the largest clinical trials in dialysis ever performed
- More Canadian participants than any other previous trial in dialysis with a similar design
- Applicable to almost all dialysis patients

6. PROJECT TIMELINE

- 2012-2016: Recruitment in Canada = largest to date, inclusion of new centers
- Publications
- Regulatory and ethics approval internationally
- Drug supply
- Ongoing recruitment targets

7. COMMENTS

ClinicalTrials.gov
https://clinicaltrials.gov/ct2/show/NCT03020303