

Dialysate Bicarbonate Trial

Pragmatic, two-arm, parallel-group, open label, individual-randomized, superiority, multicentre trial

Trial Details

Research Question: To determine if providing a lower versus higher concentration of dialysate bicarbonate (32 versus 38 mmol/L) alters the risk of outcomes important to patients and their care providers.

Trial Length: Dial-Bicarb will be ongoing in your site for 4 years.

Intervention: Patients are randomized to receive a dialysate bicarbonate concentration of 32 mmol/L or 38 mmol/L.

Randomization: Patients will be randomized based on the last digit of their OHIP number.

Implementation

1) A randomization table will be provided to nephrologists/unit staff. The randomization table will outline corresponding OHIP # and dialysate bicarbonate allocation.

2) Nephrologists will make changes to patient's bicarbonate concentration (order allocated bicarbonate concentration or set up a 'per unit protocol').

3) Unit staff will be provided with a trial handout to distribute to patients twice before the start of the trial and every 6 months during the trial. **Individual consent does not need to be obtained from each patient, as approved by the REB.**

4) Unit staff will ensure that each patient is on the correctly assigned bicarbonate concentration based on the last single digit of their OHIP # for the duration of the trial (as per randomization table).

6) Unit staff will alert nephrologist if patient deviates from their assigned dialysate bicarbonate concentration. Careful attention must be paid during dialysis sessions to ensure that the entered bicarbonate settings match the concentrations ordered in the EMR by the nephrologist.

7) A designated unit staff will work with the research team to provide monthly adherence for 20 random patients (electronically/excel).

FAQ

Who is participating in this trial?

- Adult patients 18 years of age and older on hemodialysis, with a valid health card number. Patients on frequent or nocturnal hemodialysis, or those with acute kidney injury who recover kidney function are excluded.

Can patients that do not speak English, are visually impaired or require a substitute decision maker participate?

- Yes, copies of the trial handout will be provided to sites in 20+ languages. Audio recordings of the handouts are available on the website. If there are concerns with a patient's ability to understand the trial handout, please provide the handout to a substitute decision maker as done in routine care.

What are the potential risks of participating in this trial?

- This research involves no more risk to patients than would occur in usual clinical care as the two concentrations of dialysate bicarbonate are currently used throughout Canada.

Who will be compensated for this trial?

- Patients will not be compensated for the trial, as they will incur no additional expenses for participating. Dialysis units will be compensated for time spent implementing and maintaining the trial as outlined in the site agreement.

Can patients opt out of this trial?

- Patients can opt out of receiving the assigned bicarbonate concentration; however, their data will still be collected as part of routine care.

How will trial data be collected and analyzed?

- Data collected during routine care will be obtained from provincial administrative healthcare databases. The data obtained will be de-identified and will be analyzed in a privacy-compliant manner. De-identified monthly adherence data on 20 random patients will be collected by the units and provided to the research team electronically.

Can patients still participate in other trials?

- Yes, patients participating in the Dial-Bicarb trial are still able to participate in other trials.