

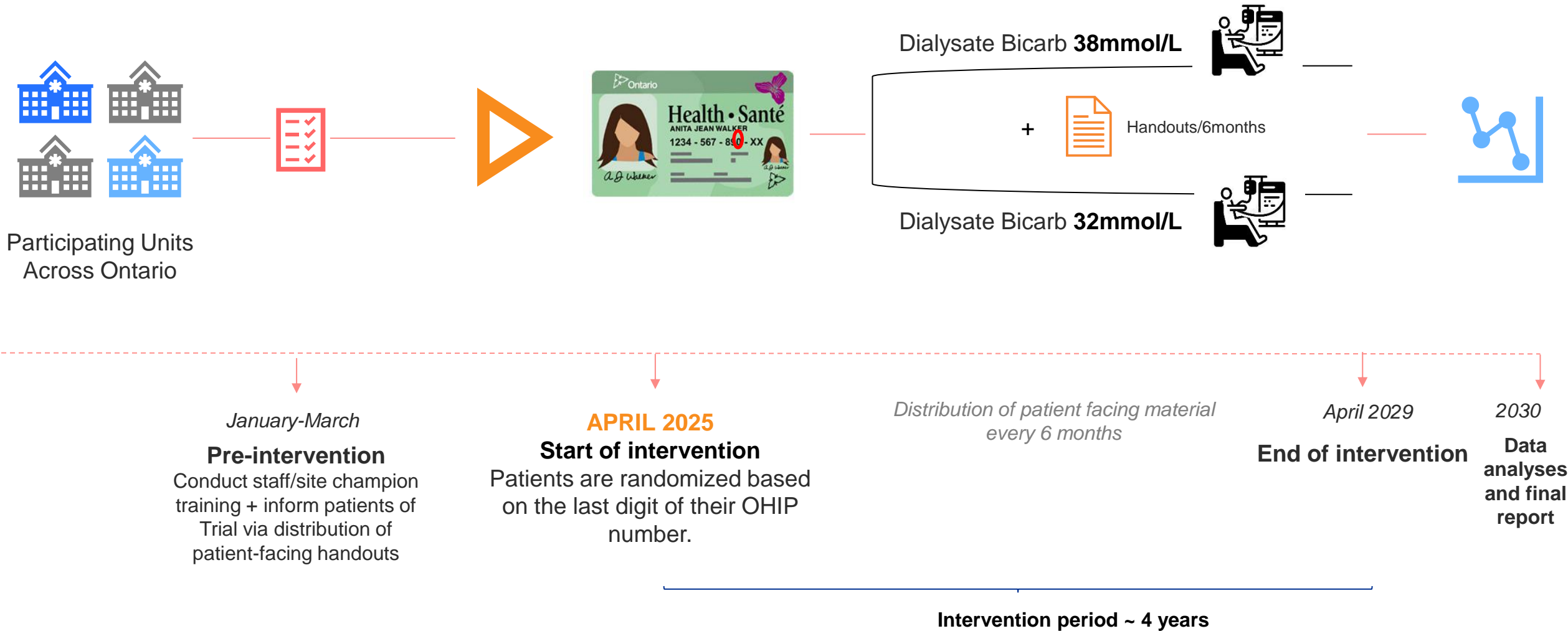
Dial-Bicarb Trial

Canada

Effects of a Lower vs. Higher Concentration of Dialysate Bicarbonate for People Receiving Maintenance Hemodialysis

DIALYSATE BICARBONATE TRIAL

Timeline



Patient Facing Material – Trial handout

- Prior to the start of the trial, a package will be sent to all participating sites. This package will include:
 - One English poster: To be placed in the unit so that it is visible to all patients
 - An English trial informational handout to be distributed to each patient in the unit
 - One copy of each of the 23 available languages, to be provided to patients who require additional languages
 - Languages are: *Tamil, Arabic, Bengali, Chinese (traditional), Chinese (simplified), Persian, French, German, Hindi, Italian, Korean, Ojibway, Oji-cree, Portuguese, Punjabi (gurmikhi), Punjabi (shahmukhi), Russian, Somali, Spanish, Tagalog, Ukranian, Urdu, Vietnamese*

We will also provide a 1-page STAFF trial information handout in this package. This is for **STAFF USE ONLY** and cannot be distributed to patients as it is not REB approved.



A Dialysis Bicarbonate Trial

What you need to know

 The fluid used in dialysis is known as dialysate. All people have bicarbonate added to their dialysis fluids. Adding bicarbonate (commonly known as baking soda) helps to balance the acidity levels in a person's blood.

 **Current Standard of Care:** Some dialysis units add bicarbonate to a concentration of 32, while others use a concentration of 38. It is unknown whether one level is better than the other for people's health.

 Your healthcare team wants to determine the **optimal amount of bicarbonate** to add to the dialysate for **best patient health outcomes**.

 You do not need to do anything other than attend your dialysis sessions. Nearly all information in this trial will be collected by your healthcare team **as part of your routine care**.

You will be asked for your consent to collect any additional information.

 Your dialysis doctor supports this trial, and will adjust your dialysis orders if they determine that you need a different level of bicarbonate than what the trial has prescribed.

 **If you do not wish to receive the trial-assigned bicarbonate level, please speak to your dialysis doctor. Opting out will not impact your overall care.**



Patients in this unit, and other units across Ontario, will be randomly assigned to one of two groups: one with a dialysate bicarbonate concentration of **32 mmol/L** and the other with **38 mmol/L**.

The trial is expected to run for **several years**.

We acknowledge the importance of understanding how to best provide dialysis care to patients who can no longer make decisions for themselves, please circulate this flyer to substitute decision-makers.

This trial was designed with the collaboration of our patient partners. We have also ensured a process that is respectful of the Indigenous peoples who are the original caretakers of this land.

If you would like to listen to a recording of the information provided in this flyer (in English and/or several other languages) please visit www.dialbicarb.ca

For any questions regarding this trial, or your participation in this trial, please contact (local PI contact XXX-XXX-XXXX) or e-mail DialBicarbCanada@lhsc.on.ca.

V 3.0 (Version Date: 09/09/2024)

Patient Trial Information Poster and Flyer, will be posted in all participating units and handed out to patients:

- One time prior to the start of the trial (**February 2025**)
- At the first of the trial (**April 2025**)
- and then every six months after start of intervention.

All eligible patients in participating units are part of the trial. The trial was granted a waiver of individual consent to provide the intervention and collect data, but patients have the option of opting out of receiving their allocated dialysate bicarbonate concentration if they choose to.

For the first package that the site receives, the package will contain enough handouts for the first 2 planned distribution periods (Feb/April)– place in the unit to store handouts?

Accessibility

- Trial handout to be distributed to SDM if applicable
- Staff to provide non-English speaking patients with the appropriate translated handout (provided as part of the package) to ensure all patients are appropriately informed of the trial
- If patients have any questions about the trial, they can:
 - Reach out to study team via email (provided on handout)
 - Visit the study website www.dialbicarb.ca for more information on the trial, and to access written and audio translations for the handout



FOR STAFF USE ONLY

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.

Any Questions/Concerns? Email: dialbicarbcanada@lhsc.on.ca

Trial information handout – for staff use:

- Summarizes key points pertaining to the Dial-Bicarb trial and how it will affect sites during implementation
- Can be distributed to relevant staff in the unit in preparation for trial implementation (prior to April 2025)
- Contains study email

Not to be distributed to patients; not REB approved for patient distribution.

Adherence

- Collected once a month for the trial duration, beginning in April 2025
- Collecting adherence data for 20 random patients
 - A list of random patient numbers will be generated by the coordinating centre and provided to the Site Champion for each adherence report
- Excel sheet will be emailed to the site champion, requesting the following data to be collected for each patient:
 1. The last digit of the patient's OHIP number
 2. The concentration of the Dialysate Bicarbonate that the patient received; this data will either be obtained from the patient's runsheet/flow chart (if applicable) or from the machine directly

We may reach out if adherence is below 90% (less than 18/20 patients being adherent)

Adherence Excel Sheet



Version date: 12 Nov, 2024

Collection of Patient-Assigned Dialysate Bicarbonate Concentration

Name of HD Unit/Centre:

Form completed by (*first and last name*)¹:

Date of form completion:

¹ I/We confirm that the information provided in this document is accurate, correct and complete and collected in accordance with the study protocol.

Patient Number	Last OHIP Number	Current Patient Dialysate Bicarbonate Concentration* *Dialysate bicarbonate concentration assigned on hemodialysis machine
1		
2		
3		