CIHR IRSC Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

Réseau de recherche sur les données de santé du Canada
Health Data Research Network Canada

Schulich MEDICINE & DENTISTRY

London Health Sciences Centre Research Institute

DIALEX

DIALysis with EXpanded solute removal

A large, simple, randomized controlled trial to evaluate the major health effects of expanded versus conventional hemodialysis

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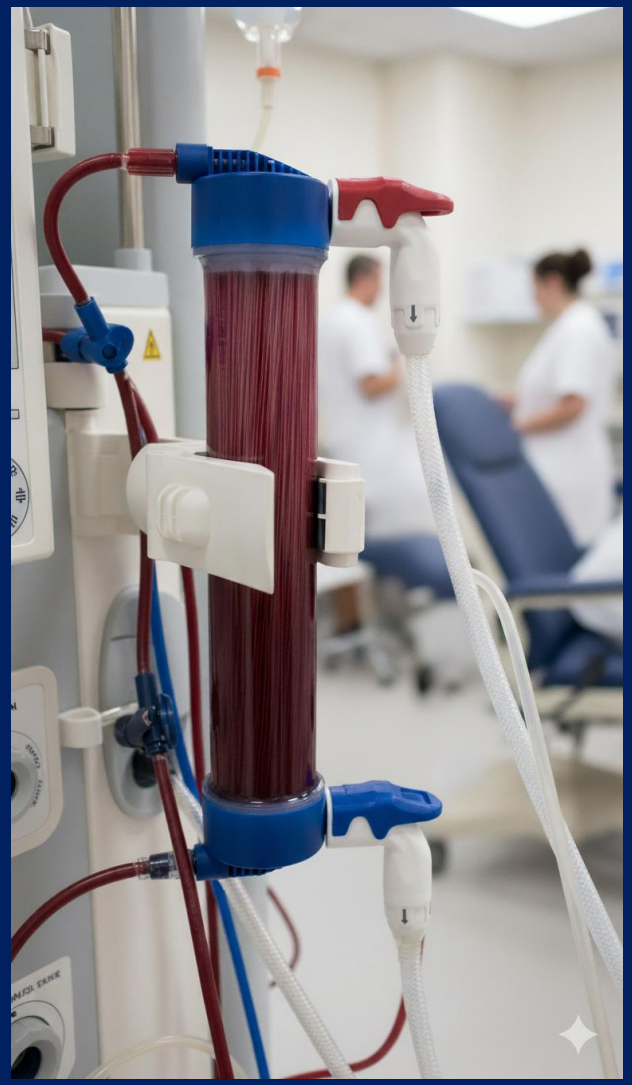
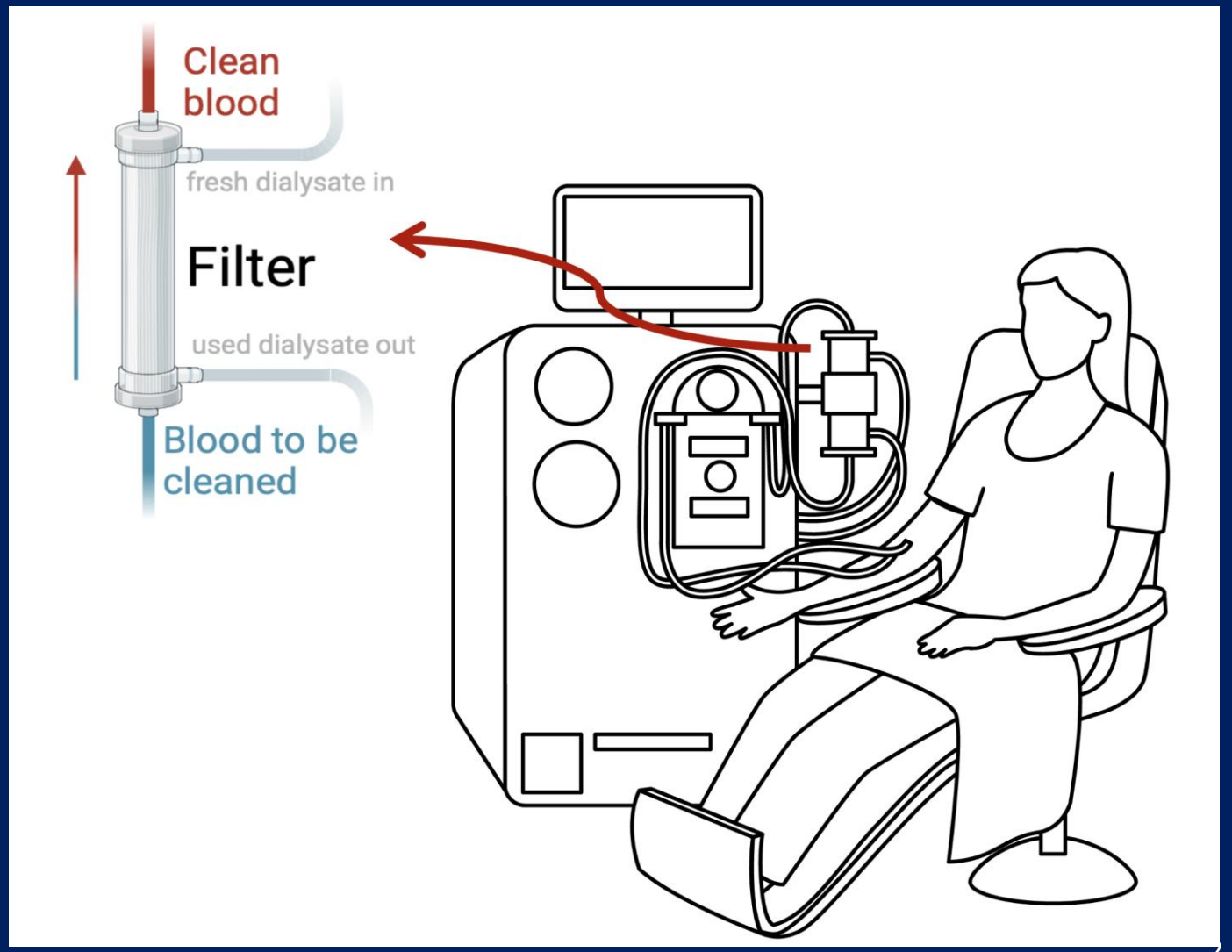
DIALEX compares dialyzers head-to-head





Clinical autonomy: an illusion

- Dialyzer availability differs by hospital
- Care providers have restricted options
- Patients are never asked
- Marketing and vendor lock-in
- Similar for many other consumables

Absence of evidence removes autonomy from patients and providers

INDIVIDUAL RANDOMIZATION OF 4800 PTS

EXPANDED iHD
(Elisio HX)

R

CONVENTIONAL iHD
(any high-flux dialyzer)

Outcomes ascertained using health card number

All-cause mortality (StatsCan)

Hospitalizations (CIHI)

Costs (ICES)

…and OPT-OUT consent model

DIALEX

DIALYSIS WITH EXPANDED SOLUTE REMOVAL

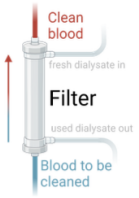
IMPORTANT NOTICE ABOUT YOUR PARTICIPATION IN A DIALYSIS FILTER STUDY

A simple study aiming to improve the health of patients on hemodialysis. Designed by kidney specialists, researchers, hospital administrators and patients on dialysis.

You will be enrolled in this study unless you explicitly decline participation - please read information below to find out more.

Patients in this unit will have an opportunity to participate in a large research study called DIALEX comparing 2 types of dialysis filters that are currently available for use across Canada. The DIALEX research team wants to find out *if using a filter with larger pores will improve patient health.*

What is a dialysis filter?



A dialysis filter *is like an artificial kidney*. It is a small tube that is always used in dialysis machines **to remove wastes and toxins** from the blood and is discarded after each use.

All DIALEX participants will be assigned by random chance to receive **one of two types of filters** during their regular hemodialysis sessions:

COMMONLY USED FILTER
(High-Flux)

- Approved by Health Canada
- Currently used in most facilities
- Removes some wastes and toxins from the blood

FILTER WITH LARGER PORES
(Super High-Flux)

- Approved by Health Canada
- Currently used in some facilities
- Removes more wastes and toxins from the blood in the same amount of time

How can the DIALEX study make a difference?

SCAN ME

If a large, high-quality study shows that one type of filter is more beneficial that the other, more people could have access to better dialysis filters. Learn more by visiting www.dialex.study or scanning the QR code.

HOW TO PARTICIPATE

If you would like to participate in this study, **just continue attending your regularly scheduled hemodialysis sessions as usual - nothing further is required on your end.** Your dialysis care physician will ensure the study is a good fit for you and will work with the central study team to ensure your participation in the study.

What will change for me if I choose to participate?

A different filter may be used in your regular hemodialysis sessions. Your dialysis sessions will **not be longer**, and **no additional visits** or tests will be required. The study is expected to last several years. You can choose to stop participation at any time by letting your healthcare team know.

What are the potential risks?

The filters being compared in this study **are currently used across Canada**. Sometimes, dialysis filters are changed in routine care outside of this study. Participation in this study **poses no more risk than expected in routine care.**

What data will be collected for the study?

Nearly all information will be collected as part of your routine care. Participants' health card numbers will be collected centrally and used to securely access and link routinely collected health data. **Access to personally identifying information will be restricted to authorized individuals only.**

If you have any questions, please speak with your dialysis care physician or contact: *[Local contact (PI or delegate)]*

If you have questions about your rights as a participant or the conduct of the study, please contact: [REB contact info]

HOW TO DECLINE PARTICIPATION

Patients who do not decline participation will be a part of the study**. If you do not wish to participate in this study**, please let your dialysis care providers know by completing the section below and returning this handout to your unit by:

[DATE stamp]

This decision will not affect your routine care or your relationships with the care providers.

I, _____, _____, **DO NOT** wish to participate.

[Print Full Name] *[Age]*

Date declined: _____

Notification → 14 days to decline

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254 patients randomized in the first month in 4 units without research staff

IS ALTERATION OF CONSENT APPROPRIATE?

Minimal risk beyond usual care

Unlikely to adversely affect welfare

Otherwise impossible or impracticable

Plan to provide a debriefing that may also offer participants the possibility of refusing consent

13 NATIONAL/REGIONAL GUIDELINES

1 INTERNATIONAL GUIDELINE

APPLICABLE TO 39 COUNTRIES