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A retrospective comparison of two types of dialysis machine for dialysis patients

Submission date	Recruitment status	[_] Prospectively registered
11/08/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/08/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/03/2022	Urological and Genital Diseases	

Plain English summary of protocol
Background and study aims
Dialysis is a procedure to remove waste products and excess fluid from the blood when the kidneys stop working properly. It often involves diverting blood to a machine to be cleaned. Normally, the kidneys filter the blood, removing harmful waste products and excess fluid and turning these into urine to be passed out of the body.
The aim is to determine whether there are differences in the clinical outcomes of expanded hemodialysis (HDx) by Theranova® compared with conventional hemodialysis (HD) with high-flux dialysis machines in Colombia.

Who can participate?
Patients who underwent dialysis for at least 90 days between 01 September 2017 and 30 November 2017.

What does the study involve?
Review of patient records for outcomes at 2 years after dialysis.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Renal Therapy Services (Colombia)

When is the study starting and how long is it expected to run for?
May 2020 to December 2020

Who is funding the study?
Renal Therapy Services (Colombia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
RCS2020-001

Study information

Scientific Title
Effectiveness of expanded hemodialysis (HDx) in Colombia: A retrospective clinical outcomes study

Acronym
COREXH-E

Study objectives
Expanded hemodialysis (HDx) could decrease frequency of hospitalization, hospital days and mortality compared with hemodialysis with high flux dialyzer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/05/2020, Fundación Cardioinfantil Ethics committee (Bogota street 163A #13B-60, Bogotá, Colombia; +57 16672727; eticainvestigacion@cardioinfantil.org), ref: 15-2020

Study design
Retrospective observational multicentre cohort study

Primary study design

Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
End stage renal disease (Hemodialysis patients)

Interventions
Patient Population: Prevalent HD patients will be entered into two cohorts and followed for 2 years
Cohort 1: patients who receive treatment with HDx using Theranova dialyzers. These patients were enrolled in the original COREXH registry between 1st of September of 2017 until 30 of November of 2017.
Cohort 2: patients from the same clinics and time frame as Cohort 1 who receive treatment via conventional HD using a high-flux dialyzer. Patients with a high comorbidity index who were not expected to survive 6 months according to clinic notes will be excluded from Cohort 2 to control for exclusion of patients (with a life expectancy of less than six months as determined by his/her attending physician) in Cohort 1 of the COREXH registry.

Test and Observation Schedule: Patients in this study were either enrolled in COREXH registry study between 1 September and 30 November 2017 or received conventional High-Flux HD during the same time period. Cohort assignment will be determined according to whether the patient was prescribed with HDx during that period, or instead remained prescribed with high-Flux HD. After the enrollment date, each patient will be followed for two years, with the end date of follow-ups within the study on November 30, 2019.

Statistical Methods: Variables will be analysed descriptively and summarized for all eligible patients with available data. Continuous variables will be summarized by sample size (N), mean, standard deviation, median, minimum, maximum and compared using t tests with p values. Frequency and percentages will be provided for categorical variables and compared using chi-square test with p values.
Weighted samples (with IPTW) will be used for the cohort´s comparisons. For comparing hospitalization, mortality and non-fatal cardiovascular events between HDx and HF HD groups, Inverse probability of treatment weighting (IPTW) using the propensity score will be conducted according to the baseline variables that might indicate potential confounding within exposure and outcomes. The propensity score will be estimated using a multivariate logistic model in which the baseline variables (at the time of inclusion to the cohort) were predictors of the exposure status. After estimating the propensity score, the IPTW for each individual subject will be calculated, the balance of the baseline variables with standardized differences less than 0.1 will be evaluated.
Incidence rates for each group will be estimated; survival functions will be calculated using Kaplan-Meier estimators; comparisons of survival functions will be performed.

Additionally, statistical modelling will be performed on all patients to evaluate clinical outcomes. Hazard-Ratios (HRs) for comparing hazards between HDx and HF HD groups will be estimated using proportional hazards after adjusting for potential confounders.For variables related with count outcomes (e.g. days of hospitalization, number of phosphorus chelating agents, antihypertensive drugs and nutritional supplements), According to overdispersion

assumption Poisson or negative binomial regression models will be used to estimate the strength of the association between type of dialysis and counts of events after adjusting for potential confounders.

Intervention Type
Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
1. Theranova dialyzer 2. Revaclear dialyzer 3. Polyflux dialyzer

Primary outcome(s)
Measured using patient records at 2 year follow up:
1. Hospitalization events
2. Days spent in hospital

Key secondary outcome(s))
Measured using patient records at 2 year follow up:
1. Mortality
2. Medication consumption

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. End stage renal disease
2. Prevalent HD patient defined as having received HD for 90 days or more at the time of the cohort's inception (01 September 2017 through 30 November 2017)
3. Enrolled in the COREXH registry between 01 September 2017 and 30 November 2017, or were treated via conventional high-flux HD during the same time period at the same renal centers, and with the same model of dialysis care
4. Undergoing HD at least 3 times per week and a minimum duration of 4 hours per session
5. Received dialysis treatment in a renal clinic that meets water quality standards established by the Association for the Advancement of Medical Instrumentation (AAMI)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1098

Key exclusion criteria
1. High comorbidity measured as Charlson comorbidity Index > 8 and patients who were not expected to survive 6 months
2. Metastatic disease
3. Pregnancy
4. Younger than 18 years old

Date of first enrolment
01/08/2020

Date of final enrolment
15/09/2020

Locations

Countries of recruitment
Colombia

Study participating centre
Renal Therapy Services dialysis network Colombia
Transversal 23 N 97-73 floor 6
Bogota
Colombia
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Sponsor information

Organisation
Renal Therapy Services

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Renal Therapy Services

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	medium cutoff (MCO) versus high-flux (HF) dialysis membranes results	07/02/2022	23/02/2022	Yes	No