ISRCTN21098097 https://doi.org/10.1186/ISRCTN21098097

Efficacy, safety and cost of expanded hemodialysis using Theranova dialyzer in Colombia

Submission date 19/03/2024	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/03/2024	**Overall study status** Completed	
Last Edited 25/03/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The expanded hemodialysis available by Theranova® dialyzer allows larger medium molecules to be removed during the hemodialysis procedure. Theranova® is a single-use hollow fiber dialyzer, with improved removal of medium-large molecules up to 45 kDa, selectively maintaining essential proteins such as albumin. Recent research indicates that there is lower mortality and hospitalization in patients using Theranova membranes compared to other high-flux dialyzers. The objective of this study is to determine the efficacy and safety of dialysis therapy in two real-life cohorts, one with hemodialysis using high-flux dialyzers (HF HD) and the other with expanded hemodialysis (HDx) using a Theranova dialyzer, in a network of renal clinics in Colombia, as well as to describe the resource consumption from the dialysis provider's perspective for this type of hemodialysis treatment.

Who can participate?
Patients aged 18 years old and over with prevalent chronic kidney disease on hemodialysis

What does the study involve?
Participants will be enrolled in the two cohorts:
Cohort 1 (HDx Cohort): Patients receiving HDx treatment on Theranova dialyzers at baseline. The cohort enrollment window will be between April 1, 2024, and April 30, 2024; the date of enrollment will be the date of signing the informed consent to participate in the study, and baseline measurements will be performed within the following seven (7) calendar days.
Cohort 2 will consist of patients receiving conventional HD treatment with an HF HD at the time of enrollment. The cohort enrollment window will be between April 1, 2024 and April 30, 2024; the date of enrollment will be the date of signing the informed consent to participate in the study and baseline measurements will be performed within the following seven (7) calendar days.

A stratified random sample of patients from the participating nephrology clinics who meet the study criteria will be selected. A total of 300 patients will be selected, i.e. 150 patients for each cohort (HDx or HF HD). Six renal clinics will provide 50 patients each. Patients selected in the

stratified random sampling will be invited to participate after an informed consent process. Patients will continue to receive their usual treatment as prescribed by their treating nephrologist (HDx or HF HD). Clinical laboratory measurements will be performed routinely every 4 weeks to evaluate the efficacy of the hemodialysis membranes. In addition, some quality-of-life surveys (baseline and 12 weeks), pruritus (baseline and 12 weeks), recovery time after hemodialysis (every 4 weeks) and restless legs syndrome (baseline and 12 weeks) will be conducted. All adverse events, whether related to the hemodialysis procedure, that occur in patients will be documented from the time the informed consent is signed until the day their follow-up in the study ends.

What are the possible benefits and risks of participating?
One of the benefits of participating in this study may be that the research staff will be able to proactively learn about some aspects of a participant's condition during the study period, allowing them to better monitor their health and adjust their treatment if needed. The results of this study may help to implement new programs for hemodialysis patients; therefore, in addition to the personal benefit described, the contribution to society would be significant.

No direct risks to health are anticipated other than those already present due to the medical condition and hemodialysis program. If events occur that alter the stable medical condition, such as requiring hospitalization, the usual treatment and referral protocol will be followed within the chronic hemodialysis program.

Where is the study run from?
Six kidney clinics in Colombia in the cities of Bucaramanga and Bogota, belonging to Renal Care Services (RCS)

When is the study starting and how long is it expected to run for?
April 2024 to July 2024

Who is funding the study?
Baxter Healthcare Corporation

Who is the main contact?
Dr Juan Carlos Mario Castillo (Principal investigator), juan_castillo@baxter.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
RCS2023-002

Study information

Scientific Title
Efficacy, safety and resource consumption of expanded hemodialysis therapy with Theranova in a Colombian dialysis network: a cohort study

Acronym
COREXH-GREEN

Study objectives
The study hypothesises that expanded hemodialysis, available with Theranova, is effective and safe compared to conventional high-flux membrane hemodialysis, and also reduces resource consumption.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/02/2024, Cardioinfantil Foundation - La Cardio (Calle 163A N 13B 60, Bogota,DC, 1113111, Colombia; +576016672727; eticainvestigacion@lacardio.org), ref: CEIC-058-2024

Study design
Observational multicentre cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Medical and other records, University/medical school/dental school

Study type(s)
Screening

Participant information sheet

Not available in web format

Health condition(s) or problem(s) studied
Prevalent patients on hemodialysis

Interventions
This study primarily aims to determine the efficacy and safety of dialysis therapy in two real-life cohorts, one with hemodialysis using high-flux dialyzers (HD HF) and the other with expanded hemodialysis (HDx) using the Theranova dialyzer, in a network of renal clinics in Colombia. The study will also describe the resource utilization from the dialysis provider's perspective for this type of hemodialysis treatment.

Two cohorts will be followed: the first HDx (hemodialysis with Theranova dialyzer prescribed 3 times per week with a minimum of 4 hours per session) and the second HF HD (high flow hemodialysis prescribed 3 times per week with a minimum of 4 hours per session) in six renal clinics in Colombia. Patients will be followed for 12 weeks. As this is an observational study, there will be no intervention by the researchers. Permuted block random sampling will be used to select study participants. The cohorts will be defined according to the type of dialyzer they are using at the time of inception (HD AF or HDx). Since this is a real-life study, the details of the prescription of the type of dialyzer as well as the characteristics of the therapy will depend entirely on the treating nephrologist who will have complete freedom to make such a prescription according to best practices, dialysis clinics and the availability of technologies in each of their kidney clinics.

The study population comprises prevalent chronic HD patients (those with 90 days or more on this dialysis therapy), belonging to 6 renal clinics of the Baxter Renal Care Services renal clinic network served in the cities of Bogotá and Bucaramanga. The renal clinics selected to participate in the study are RTS Bucaramanga; RTS Soacha, RTS Agencia San Rafael; RTS National University agency, RTS National Kidney Institute and RTS Cardio-Children Foundation. 300 patients will be enrolled in the study.

In this study, the research team will:
1. Describe the demographic and clinical characteristics of both cohorts (HDx and HD HF), estimate and compare the effectiveness of HD HF and HDx procedures using indicators such as single pool Kt/V, hemoglobin levels, phosphorus, iPTH, serum albumin, high-sensitivity CRP, kappa and lambda free light chain reduction ratio, beta-2 microglobulin reduction ratio, and leptin reduction ratio.
2. Compare the efficacy of HD HF versus HDx in terms of post-dialysis recovery time, diagnostic criteria for restless legs syndrome, pruritus scale, quality of life as measured by the KDQoL SF-36 and EQ-5D-5L instruments, and patient-reported outcomes using the PROMIS instrument.
3. Estimate the frequency of adverse events in the study cohorts and those related to the dialysis procedure.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Effectiveness measured using the reduction ratio of Beta-2 microglobulin in serum measured using the Immunoturbidimetric test at week 4 and week 12
2. Effectiveness measured using the reduction ratio of Kappa-free light chains in serum measured using turbidimetry technique at week 4 and week 12

3. Effectiveness measured using the reduction ratio of Lambda free light chains in serum measured using turbidimetry technique at week 4 and week 12
4. Effectiveness measured using the reduction ratio of leptin in serum measured using ELISA test at week 4 and week 12
5. Change from a baseline value of Kt/V single pool, hemoglobin, phosphorus, iPTH, serum albumin and high-sensitivity CRP measured using means difference at 4, 8, and 12 weeks of follow-up
6. The incidence of adverse events and serious adverse events measured according to the International Classification for Patient Safety 1.0 of the Global Alliance for Patient Safety WHO, adapted to Colombia. Events data collected in study records during follow-up. Where the numerator is made up of the number of adverse events and the denominator is made up of the total number of patients at risk.

Secondary outcome measures
Secondary outcomes:
1. Post-hemodialysis session recovery time measured using data collected from patient medical records at baseline, 4, 8, and 12 weeks
2. Pruritus measured using the Pruritus scale at baseline and 12 weeks
3. Restless legs syndrome measured using the Diagnostic criteria for restless legs at baseline and 12 weeks
4. Quality of life measured using the KDQoL SF 36 and EQ-5D-5L instruments at baseline and 12 weeks
5. Physical, mental, and social health reported by patients with the PROMIS 29 instrument at baseline and 12 weeks

Exploratory Evaluations:
1. Non-fatal cardiovascular events and mortality measured using data collected from patient medical records during follow-up
2. Resource use for the HD AF or HDx procedure from the provider's perspective. Case methodology will be used to establish the direct cost of a hemodialysis session with an HF dialyzer using a dialysate flow of 400 and 500 ml/hour and it will be compared with the cost of performing an expanded hemodialysis session with a Theranova dialyzer.

Overall study start date
15/01/2024

Completion date
31/07/2024

Eligibility

Key inclusion criteria
1. Patients 18 years of age and older
2. Patients diagnosed with chronic kidney disease (CKD) in renal failure with more than 90 days of chronic hemodialysis
3. Receiving HD at least 3 times per week for a minimum of 4 hours per session
4. Be treated at one of the 6 renal clinics selected to participate in this study
5. Have a vascular access arteriovenous fistula or graft

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
85 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Pregnancy
2. High comorbidity as measured by Charlson Comorbidity Index > 8 and patients not expected to survive more than 6 months
3. Metastatic disease
4. Patients with sensory or cognitive impairment that prevents them from responding to the surveys.
5. Patient who does not provide informed consent to participate in the study

Date of first enrolment
01/04/2024

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
Colombia

Study participating centre
RTS Sucursal Instituto Nacional del Riñón
Calle 78 N 23-40
Bogota,DC
Colombia
1110911

Study participating centre
RTS Agencia San Rafael
Carrera 8 N 17-44 sur
Bogota,DC

Colombia
1113111

Study participating centre
RTS Sucursal Bucaramanga
Transversal 93 # 34-99
local SS10-A-B-C-D centro comercial el cacique
Bucaramanga
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680006

Study participating centre
RTS Agencia Universidad Nacional
Calle 44 # 59-75, piso 1, consultorios 26 y 27
Bogota,DC
Colombia
111711

Study participating centre
RTS Agencia Cardioinfantil
Carrera 14ª#163ª-98
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Study participating centre
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Sponsor information

Organisation
Baxter (United States)

Sponsor details

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
Baxter Healthcare Corporation

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication. The anonymized database will be available to share upon request to the principal investigator via email juan_castillo@baxter.com. It will only be shared after the article is published in a scientific journal.

IPD sharing plan summary

Available on request, Published as a supplement to the results publication