ISRCTN45211359 https://doi.org/10.1186/ISRCTN45211359

Expanded hemodialysis registry protocol in Colombia

Submission date
14/08/2017

Recruitment status
No longer recruiting

Registration date
16/08/2017

Overall study status
Completed

Last Edited
28/03/2022

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic kidney disease and acute kidney injury cause the kidneys to lose their ability to filter and remove waste and extra fluid from the body. Hemodialysis is a process that uses a man-made membrane to remove waste and extra fluid from the blood. The new generation of dialysis membranes have improved the clearance of larger waste molecules (expanded hemodialysis). These improvements need to be evaluated in terms of their effects on hospitalization rates, mortality (death rates), cardiovascular (heart) events and quality of life. The aim of this study is to assess the clinical outcomes of patients treated with expanded hemodialysis, using a registry (database) of conventional clinical practice in Colombia.

Who can participate?
Patients aged 18 and over with chronic kidney disease who are receiving expanded hemodialysis treatment

What does the study involve?
The study data is taken from the patient's electronic medical record system. The data includes: demographic data (date of birth, age, sex), medical history, hemodialysis data, laboratory test results, quality of life, nutritional information, survival, hospitalization, mortality rate, non-fatal cardiovascular events rate, and side effects.

What are the possible benefits and risks of participating?
This is an observational study and there are no risks for the participants.

Where is the study run from?
Renal Therapy Services Colombia network

When is the study starting and how long is it expected to run for?
September 2017 to December 2018

Who is funding the study?
Baxter Healthcare Corporation (USA)

Who is the main contact?
Mauricio Sanabria
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RTSCOL003

Study information

Scientific Title
Expanded hemodialysis registry protocol in Colombia (COREXH): a prospective cohort, multicenter, observational study

Acronym
COREXH

Study objectives
Hemodialysis is a procedure that removes different electrolytes, toxins and excess fluid from the patient's general circulation when they cannot be excreted normally due to deterioration of chronic kidney function. Recently, a new generation of dialyzers with medium cut-off points removes high molecular weight toxins such as cytokines, myoglobin, and free light chains. Any increase in the clearance of these substances could improve the state of inflammation and malnutrition and correlate with an improvement in symptoms that implies that patients report better health status and quality of life.

General objective:
1. Determine clinical outcomes in patients on treatment with expanded hemodialysis using the Theranova dialyzer, based on a registry of conventional clinical practice in Colombia

Specific objectives:
1. Describe the demographical and clinical characteristic of the population under study
2. Establish mortality rates, rates of non-fatal cardiovascular events, hospitalization rates during

the 12-month prescription of expanded hemodialysis therapy
3. Describe patient-reported outcome measures such as dialysis symptom index, diagnostic criteria for restless legs, and quality of life related to health
4. Compare the behavior over time of clinical and laboratory variables according to different groups of patients determined by: vintage in therapy, comorbidities, causes of chronic kidney disease and comorbidity scores
5. Describe efficacy outcomes used in the practice of usual chronic hemodialysis, such as: anemia profile, lipid profile, inflammatory markers, nutritional parameters, Kt/V, phosphorus, albumin behavior and variation of residual renal function
6. Describe patterns of medicine use, such as: erythropoietin and iron doses, nutritional supplements, phosphorus binders and number of antihypertensive drugs, and daily tablet/pill consumption
7. Evaluate patient safety with expanded hemodialysis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical research ethics committee of Renal Therapy Services, 01/08/2017, ref: 007

Study design
Prospective cohort multicenter observational study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
End stage renal disease with hemodialysis

Interventions
The study data will be exported directly from the patient's electronic medical record system (Versia®) by Renal Therapy Services. The study data that normally do not belong to the patient's Versia record shall be entered by the center's staff to an Excel sheet with a default format.

Demographic, clinical characteristics data and clinical outcome:
1. Demographic variables: identification of the subject within the study, date of birth, age, sex
2. Medical history variables: cause of the chronic kidney disease (CKD), prior hypertension diagnosis, prior diabetes diagnosis, prior cardiovascular disease diagnosis, Charlson Index adapted to CKD, Karnofsky performance status scale, date of initiation of chronic renal replacement therapy and vintage in dialysis therapy
3. Hemodialysis variables: hemodialysis session duration, number of sessions per week, dialysis machine name, hemodialysis machine technology used, blood flow velocity (QB), dialysate liquid velocity (QD), ultrafiltration, pre-dialysis weight, post-dialysis weight, dry weight, type of vascular access, type of extracorporeal circuit anticoagulation. Total volume of blood treated, systolic blood pressure , diastolic blood pressure , heart rate, respiratory rate, temperature. They will be taken for each session
4. Laboratory variables: the measure frequency is adjusted to RTS Colombia's clinical practice standards: hemoglobin, hematocrit, platelets, lymphocytes, potassium, calcium, phosphorus,

albumin, pre and post BUN, pre and post Urea, single pool Kt/V, ferritin, iron, transferrin saturation percentage, TIBC, UIBC, PTHi, total cholesterol, HDL cholesterol, LDL cholesterol, triglycerides, ultra-sensitive CRP, residual renal function (creatinine clearance and urea clearance)
5. Patient-reported outcome measures (PROMs): KDQOL-36™ Quality of Life, Dialysis Symptoms Index, and Restless Legs Diagnostic Criteria; periodicity is baseline, 6 months, and 12 months
6. Nutritional assessment variables: malnutrition-inflammation score, energy protein wasting score and protein catabolic rate. The periodicity conforms to RTS Colombia's clinical practice standards
7. Outcome variables: survival, hospitalization rate, hospital days, time until first hospitalization, mortality rate and non-fatal cardiovascular events rate
8. Safety variables: adverse events
9. End-of-follow-up variables: cause of end of follow-up and date of end of follow-up

Safety assessments:
The researcher or designee will expressly and actively inquire about adverse events (AE) and record them from the moment the informed consent form is signed until the study is completed or the subject withdraws his/her consent and/or the researcher removes him/her from the study. Additionally, the researcher or designee shall record and verify any AE that the subjects report on a voluntary basis.

Statistical methods:
1. Two types of statistical approaches will be performed, one of intention of treatment in which all the patients who have received expanded hemodialysis treatment with the Theranova dialyzer (medium cut-off dialyzer) for at least one week will be analyzed; and with at least three months of follow-up within the study; patients with less time of treatment and less follow-up time will be analyzed for descriptive baseline effects but not for analysis contemplated in the study
2. Safety analyzes will be performed on all patients admitted to the study
3. A protocol approach will be performed with the subset of patients who received all treatments with the Theranova dialyzer (medium cut-off dialyzer) during the follow-up period, or until an outcome is present
4. Continuous variables will be summarized by descriptive statistics according to the data distribution: mean and median (standard deviation and interquartile range). In addition, graphical tools will be used to complement the description (boxplots and histograms)
5. The qualitative variables will be summarized by measures in frequencies and percentages and graphically as bars. For the description of the behavior of some variables over time. In addition to the summary statistics will be used two-way graphs in which the X axis will present the time in follow-up and the Y axis the values of the variables of interest in each one of the measuring points
6. Incidence density rates will be estimated in which the numerator is constituted by the number of events and the denominator by the time contributed by each patient in the study. These times can be variable from patient to patient depending on the possibility of censorship to the right. These rates will be presented with their respective 95% confidence intervals
7. Mixed models will be used to explore the trajectory of levels of continuous variables in hemodialysis that are taken at different time points, such as UF, Albumin, Hemoglobin, Kt/V contributed in session, serum phosphorus, serum calcium and C reactive protein. In addition, these models will allow the comparison of variables dependent on variables of some interest variables (vintage in therapy, comorbidities, causes of chronic kidney disease and comorbidity scores)

Intervention Type

Other

Primary outcome(s)
Effectiveness assessments:
1. The rates of hospitalization and hospital days
2. Mortality rates
3. Rates of non-fatal cardiovascular events
Exported directly from the patient's electronic medical record system; the follow-up is 1 year.

Key secondary outcome(s))
1. Patient-reported outcome measures: individual item scores and total scores for Dialysis Symptom Index (DSI) and quality of life (KDQOL-36™) and frequency of restless legs diagnosis
2. Number of uses of phosphorus chelating agents and plasma phosphorus level
3. ESA dose, type and route of administration and hemoglobin level
4. Number of antihypertensive drugs and systolic and diastolic blood pressure
5. Intake of tablets/pills per day and KDQOL-36™ Score
6. Use of nutritional supplements and nutritional status
Exported directly from the patient's electronic medical record system; the follow-up is 1 year.

Completion date
30/12/2018

Eligibility

Key inclusion criteria
1. The subject or a legally authorized representative has signed the written informed consent form
2. The subject is ≥ 18 years old
3. The subject has been diagnosed with CKD with more than 90 days in chronic hemodialysis
4. The subject has been receiving expanded hemodialysis treatment in a renal clinic of the RTS network with the Theranova® dialyzer
5. The subject has been undergoing a hemodialysis schedule at least 3 times per week and a minimum duration of 4 hours per session
6. The subject is being dialyzed 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

Lower age limit
18 years

Sex
All

Total final enrolment
992

Key exclusion criteria
1. The subject has a life expectancy of no more than six months as determined by his/her attending physician
2. The subject has or had an active infection diagnosed in the past 4 weeks

Date of first enrolment
04/09/2017

Date of final enrolment
30/11/2017

Locations

Countries of recruitment
Colombia

Study participating centre
Renal Therapy Services Colombia network
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Sponsor information

Organisation
Baxter Healthcare Corporation

ROR
https://ror.org/02d6ew870

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mauricio Sanabria (mauricio_sanabria@baxter.com). Study data will be protected under strict rules of confidentiality.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results on impact of medium cutoff (MCO) membranes on clinical outcomes and safety	29/05/2020	28/03/2022	Yes	No
Results article	results on impact of medium cutoff (MCO) membranes on patient-reported outcomes	11/11/2020	28/03/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes