ISRCTN25749326 https://doi.org/10.1186/ISRCTN25749326

Albumin levels, inflammation and nutrition in chronic hemodialysis patients treated with medium cut-off or high-flux membranes: A cohort study

Submission date
04/03/2025

Recruitment status
No longer recruiting

Registration date
06/03/2025

Overall study status
Completed

Last Edited
05/03/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This is an analytical, multicenter, retrospective cohort study whose main objective was to establish the role of serum albumin levels, as well as markers of inflammation and malnutrition on outcomes such as mortality, non-fatal cardiovascular events, hospitalization and hospital days in hemodialysis patients treated with medium cut-off (MCO) or high-flux membranes (HD AF).

Who can participate?
Adults , preceding HD treatment > 90 days, treatment either by HDx therapy enabled by Theranova membrane or conventional HD using an high flux membrane (HF-HD) for a minimum of 4 hours, 3 times per week. The exclusion criteria were life expectancy of less than 6 months, active infection, metastatic disease, or a Charlson comorbidity index score >8.

What does the study involve?
This is a retrospective cohort study compared to patients with the same characteristics treated with conventional HF HD versus HDx. The inception phase of the cohorts was between September 1, 2017 and November 30, 2017. After cohort assembly, demographic and clinical information on each patient will be collected longitudinally over time for up to a maximum of four (4) years.Censored events were a kidney transplant, loss of follow-up, suspension of dialysis therapy, change of dialysis provider, change of dialysis modality, change of type of membrane, and recovered kidney function.

What are the possible benefits and risks of participating?
The subjects' participation in this study did not entail any direct risks to their health, other than those already existing due to their health condition and their chronic hemodialysis program. The expected benefits for the patient are less inflammation, reduction of hospitalization events and reduction of non-fatal cardiovascular events and reduction in mortality.

Where is the study run from?
Renal Care Services-Latin America (Colombia)

When is the study starting and how long is it expected to run for?
September 2017 to November 2021

Who is funding the study?
Baxter International, Inc. (USA)

Who is the main contact?
Mauricio Sanabria, mauricio.sanabria@vantive.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RCS2022-002

Study information

Scientific Title
Albumin levels, inflammation and nutrition in chronic hemodialysis patients treated with medium cut-off or high-flux membranes: A cohort study

Study objectives
There is a difference when comparing HDx versus HF-HD in terms of albumin levels, hospitalizations, non-fatal cardiovascular events and mortality.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 31/05/2023, Cardio Foundation (calle 153 No 13B-60, Bogota, 1113111, Colombia; +57 6016672727; eticainvestigacion@lacardio.org), ref: IRB00007736 minute 019-2023

Study design
Observational retrospective cohort study

Primary study design
Observational

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Hemodialysis

Interventions
Patients were divided into two cohorts: HDx and HF-HD. The use of HDx, enabled by the Theranova dialyzer, was dependent on the availability of these membranes at the clinical sites, and the prescription of membranes was at the discretion of the treating nephrologist. Demographic and clinical characteristics were assessed at baseline and every six months for a maximum of 4 years, and all data were collected from the Renal Care Services' Versia® electronic medical record system. An internal audit was performed as part of a data quality assurance process.

Intervention Type
Device

Phase
Phase III/IV

Drug/device/biological/vaccine name(s)
Theranova dialyzer and high flux dialyzers

Primary outcome(s)
1. Albumin serum (bromocresol green) was measured each six month (baseline, 6,12,18,24,30,36,42,48 months)
2. Protein-energy wasting (PEW) was measured by applying the four diagnostic criteria:
2.1. altered serum biochemistry indicated by a serum albumin level of <3.8 g/L or total cholesterol <100 mg/dL
2.2. decreased body mass status identified by a body mass index (BMI) of <23 kg/m² or <10% total body fat
2.3. muscle wasting defined by the lean tissue index
2.4. low dietary protein intake determined by the normalized protein equivalent of a total nitrogen appearance of <0.8 g/kg/day. (baseline, 6,12,18,24,30,36,42,48 months)
3. Hospitalization: defined as any hospital admission event lasting 24 hours or more. Recording the main diagnosis with ICD 10 code nomenclatura. Chronological record from day 1 to month 48 of follow-up.
4. Mortality: Death during follow-up in the study. Recording the diagnosis cause with ICD 10

code nomenclatura. Chronological record from day 1 to month 48 of follow-up.
5. Fatal major cardiovascular evento: Recording the diagnosis cause with ICD 10 code nomenclatura. Chronological record from day 1 to month 48 of follow-up. See Appendix 3 of the protocol.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
30/11/2021

Eligibility

Key inclusion criteria
1. Patients over 18 years of age.
2. Patients diagnosed with chronic kidney disease (CKD) in renal failure with more than 90 days in chronic hemodialysis.
3. Receiving HD at least 3 times per week and with a minimum duration of 4 hours per session.
4. Being treated in one of the 12 renal clinics of the Baxter Renal Care Services (BRCS) network included in the study, in the cities of Bucaramanga, Barranquilla, Medellín, Bogotá, Ibague, Armenia, Cali.
5. Being covered by one of the following health insurers: Nueva EPS, Compensar, Comparta, Comfenalco Valle and Mutualser

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
94 years

Sex
All

Total final enrolment
1092

Key exclusion criteria
1. Pregnant women.
2. Patients whose clinical history does not have sufficient information to establish their nutritional diagnosis.
3. Having a high comorbidity, measured as a Charlson comorbidity index > 8 and patients who

are not expected to survive more than 6 months.
4. Metastatic disease

Date of first enrolment
01/09/2017

Date of final enrolment
30/11/2017

Locations

Countries of recruitment
Colombia

Study participating centre
RCS Instituto Nacional del Riñón
Calle 78#23-40
Bogota
Colombia
110211

Study participating centre
RCS Agencia Cardioinfantil
Carrera 14ª#163ª-98
Bogota
Colombia
110211

Study participating centre
RCS Agencia San Rafael
Carrera 8 n° 17-44 sur entrada 3 piso 1
Barrio Sociego
Bogota
Colombia
110211

Study participating centre
RCS Agencia la Calleja
Calle 127 bis #19-25 Piso 5
Bogota
Colombia
110211

Study participating centre
RCS Sucursal Barranquilla
Calle 47 # 16-167
Barranquilla
Colombia
080003

Study participating centre
RCS Sucursal Bucaramanga
Transversal 93 # 34-99
local SS10-A-B-C-D Centro Comercial el Cacique
Bucaramanga
Colombia
680005

Study participating centre
RCS Servicios de Terapia Renal del Valle
Calle 45N # 4N -32 la Flora
Cali
Colombia
760004

Study participating centre
RCS Sucursal Medellín
Carrera 57 #44ª-10
Medellin
Colombia
050011

Study participating centre
RCS Servicios de Terapia Renal SAS
Calle 5A #42-10
cali
Colombia
760004

Study participating centre
RCS Sucursal Armenia
Carrera 6 No. 3-180 Centro Comercial Calima Local 1-14

Armenia
Colombia
630004

Study participating centre
Unidad Renal del Tolima S.A.S
calle 31 N° 4D-36 Barrio Cádiz
Ibague
Colombia
730005

Sponsor information

Organisation
Baxter International, Inc.

Funder(s)

Funder type
Industry

Funder Name
Baxter International

Alternative Name(s)
Baxter International Inc., Baxter, Baxter International Inc, Baxter Laboratories, Inc., BaxterInternational

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

Database for the study are available from the principal investigator (juan.castillo@vantive.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		28/02/2023	05/03/2025	No	No
Statistical Analysis Plan	version 1.0	28/02/2023	05/03/2025	No	No