

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

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Registration date 06/03/2025	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 05/03/2025	Condition category Urological and Genital Diseases	<input checked="" type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Contact name

Dr Juan Carlos Mario Castillo

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Additional identifiers

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, Ibagué, 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

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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 #44^a-10
Medellin
Colombia
050011

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

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