

Clearance of molecules and inflammatory markers: high-flux vs medium cut-off dialyzers

Submission date 26/11/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/12/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 03/03/2025	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Chronic kidney disease (CKD) remains a significant public health challenge, particularly among older adults. Patients on hemodialysis face elevated cardiovascular risks due to the incomplete removal of harmful substances, known as uremic toxins. The ELISIO™ medium cut-off (MCO) dialyzer aims to enhance the removal of these toxins. This study evaluates whether the ELISIO™ dialyzer is at least as effective as, or potentially better than, a standard high-flux dialyzer in removing toxins, reducing inflammation, and minimizing complications.

Who can participate?

Adults currently undergoing regular hemodialysis at least three times per week for three months

What does the study involve?

Participants are randomly assigned to use either the ELISIO™ or a standard dialyzer (NS21) for 2 weeks, then switch to the other dialyzer for another 2 weeks. Blood samples are taken before and after dialysis sessions to measure toxin levels, inflammation markers, and potential albumin loss. Adverse events and side effects are monitored and recorded.

What are the possible benefits and risks of participating?

Participants contribute to advancing dialysis treatment knowledge, potentially improving care for future patients. Risks are minimal and include standard dialysis-related side effects, such as low blood pressure or allergic reactions, observed at similar rates for both dialyzers.

Where is the study run from?

Torrecárdenas University Hospital (Spain)

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

September 2022 to July 2023

Who is Funding the study?

Nipro (Spain)

Who is the main contact?

Javier Ramírez-Santos, jrs519@inlumine.ual.es

Contact information

Type(s)

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Additional identifiers

Protocol serial number

ELISIO 110/2022

Study information

Scientific Title

Comparison of molecule clearance and pro-inflammatory markers between high-flux and medium cut-off dialyzers (ELISIO™ 21): a cross-over study

Study objectives

ELISIO™ is non-inferior to the comparator high-flux dialyzer (NS21).

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 14/09/2022, Torrecárdenas University Hospital Ethics Committee (CEIm) (C /Hermandad Donantes de Sangre s/n, Almería, 04009, Spain; +34 950 016 531; al42_cetico_chto.sspa@juntadeandalucia.es), ref: 110/2022

Study design

Randomized cross-over study

Primary study design

Interventional

Study type(s)

Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied

End-stage renal disease

Interventions

A simple randomization method was used to select participants from the eligible candidates. Group allocation, determined by the dialyzer type, was also assigned through randomization based on each patient's dialysis shift.

Participants are randomly assigned to use either the ELISIO™ or a standard dialyzer (NS21) for 2 weeks, then switch to the other dialyzer for another 2 weeks. Blood samples are taken before and after dialysis sessions to measure toxin levels, inflammation markers, and potential albumin loss. Adverse events and side effects are monitored and recorded.

Participants underwent treatment three times per week, either on Monday/Wednesday/Friday or Tuesday/Thursday/Saturday shifts. For the first two weeks, treatment was conducted using the initial dialyzer, followed by an additional two weeks with the second dialyzer.

Intervention Type

Device

Phase

Phase III

Drug/device/biological/vaccine name(s)

MCO ELISIO™ 21HX dialyzer

Primary outcome(s)

Pre- and post-dialysis levels of creatinine (mg/dL), urea (mg/dL), phosphorus (mg/dL), parathyroid hormone (PTH, pg/mL), and albumin (g/dL) measured using blood sample analysis at the laboratory of Torrecárdenas University Hospital in blood samples collected during the second weekly session of each patient

Key secondary outcome(s)

Pre- and post-dialysis levels of beta-2 microglobulin (mg/L), myoglobin (ng/mL), C-reactive protein (CRP, mg/L), procalcitonin (ng/mL), and interleukin-6 (IL-6, pg/mL) measured using blood sample analysis at the laboratory of Torrecárdenas University Hospital in blood samples collected during the second weekly session of each patient

Completion date

30/07/2023

Eligibility

Key inclusion criteria

Being on renal replacement therapy with hemodialysis for at least 3 months prior to inclusion

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

12

Key exclusion criteria

1. Patients with treatment regimens of fewer than three sessions per week
2. Minors
3. Patients hospitalized or deceased during the study

Date of first enrolment

01/10/2022

Date of final enrolment

20/10/2022

Locations

Countries of recruitment

Spain

Study participating centre
Torrecárdenas University Hospital
C. Hermandad de Donantes de Sangre, s/n
Almería
Spain
04009

Sponsor information

Organisation

Nipro (Japan)

ROR

<https://ror.org/03creg496>

Funder(s)

Funder type

Industry

Funder Name

Nipro

Alternative Name(s)

Nipro Corporation, Nipro Corp., Nipro Medical Corporation, , , Nipro Kabushiki-gaisha

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

Japan

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Javier Ramírez-Santos (jrs519@inlumine.ual.es).

IPD sharing plan summary

Available on request