ISRCTN10242184 https://doi.org/10.1186/ISRCTN10242184

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

Submission date	Recruitment status	[_] Prospectively registered
26/11/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/12/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
03/03/2025	Urological and Genital Diseases	[X] 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

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Principal Investigator

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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_cht.hto.sspa@juntadeandalucia.es), ref: 110/2022

Study design
Randomized cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet

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

Pharmaceutical study type(s)
Bioequivalence

Phase
Phase III

Drug/device/biological/vaccine name(s)
MCO ELISIO™ 21HX dialyzer

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
01/09/2022

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
13

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
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Sponsor information

Organisation
Nipro (Japan)

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Sponsor type
Industry

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https://www.nipro-group.com/

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

Publication and dissemination plan
Publication in a peer-reviewed journal

Intention to publish date
01/12/2024

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