Intradialytic monitoring of mitochondrial oxygen tension and bioimpedance.

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The general aim of the current project is to assess the feasibility of two novel monitoring techniques, intradialytic mitoPO2 monitoring and continuous bioimpedance and assess the impact of hemodialysis on mitochondrial level by studying the change...

Ethical review	Approved WMO
Status	Pending
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational non invasive

Summary

ID

NL-OMON57354

Source
ToetsingOnline

Brief title
WITNESS

Condition

- Renal disorders (excl nephropathies)

Synonym
Chronic kidney disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,AIKON Health B.V.,Photonics Healthcare B.V.

Intervention

Keyword: Bioimpedance, Hemodialysis, Mitochondria

Outcome measures

Primary outcome

The primary objectives of this study are to is to describe the effects of the HD treatment with and without ultrafiltration on the change in mitoPO2 and mitoVO2.

Secondary outcome

The secondary objectives of this study are to

- Compare pre-dialysis mitoPO2 and mitoVO2 baseline values to the values obtained in previous studies with the COMET.
- Describe the relation between changes in skin mitoPO2 and mitoVO2 and intradialytic continuous thoracic bioimpedance.
- Describe the relation between changes in skin mitoPO2 and mitoVO2 and intradialytic continuous calf bioimpedance.
- Describe the relation between changes in skin mitoPO2 and mitoVO2 and the change in extracellular resistance ratio measured at the calf
- To evaluate the change in mitoPO2 and bioimpedance prior to and after intradialytic hypotensive symptoms
- To perform validation of the TBW algorithm from the bioimpedance results by use of the Body Composition Monitor (BCM)

Secondary study parameters are

- Symptoms of intradialytic hypotension

- Interventions during HD treatment, e.g. positioning in Trendelenburg or

terminating ultrafiltration.

- Total body water from local thoracic bioimpedance measurements

- Total body water from local calf bioimpedance measurements

Study description

Background summary

The microcirculation and mitochondrial function at tissue level are altered in the dialysis population. Dialysis related bioincompatibility, decreased tissue perfusion and mitochondrial dysfunctions are causes of oxidative stress that may lead to premature cardiovascular disease (CVD) and aging. Rather than solely targeting macrocirculatory hemodynamic stability, maintaining an adequate balance of oxygen supply and demand to the tissue, might form a relevant target for prevention of organ hypoperfusion and improvement of cardiovascular outcomes in the hemodialysis population. Intradialytic monitoring with the Cellular Oxygen METabolism (COMET) that measures mitochondrial oxygen tension and consumption through the skin would provide novel information on the direct effect of hemodialysis on mitochondrial level. Since the mitochondrial oxygen tension is also dependent on the fluid state, simultaneous bioimpedance measurements would enhance our understanding of the impact of fluid removal on cellular metabolism.

Study objective

The general aim of the current project is to assess the feasibility of two novel monitoring techniques, intradialytic mitoPO2 monitoring and continuous bioimpedance and assess the impact of hemodialysis on mitochondrial level by studying the change in measured parameters during the hemodialysis treatment.

Study design

This is a prospective observational cohort study in which both intradialytic mitoPO2 and bioimpedance measurements are conducted during hemodialysis treatment.

Study burden and risks

The risks in this study are moderate, considered the hemodialysis patient population is a vulnerable group. Both monitoring devices have been

successfully applied in previous clinical studies with fragile patients, such as ICU patients. The burden for the hemodialysis patients is minimal since it concerns non-invasive measurements and the study is solely observational. The normal clinical practice will continue and will not be altered.
Patients are asked to arrive 20 minutes earlier for their hemodialysis appointment and to stay 20 minutes longer. On the other hand, patients do not need to make additional visits to the hospital for this study. Additionally, they are asked to fill out a short checklist about the symptoms of hypotension experienced during dialysis and the overall burden of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 18 years or higher.

On hemodialysis treatment for at least three months.
Receiving hemodialysis treatment three times a week.

Exclusion criteria

Major limb amputations.
Presence of cardiac implants.
Skin conditions aggravated by sunlight or increased sensitivity to light.
Hypersensitivity to 5-aminolevulinc acid.
Pregnanty or breastfeeding.
Insufficient comprehensibility of the Dutch or English language.
Porphyria.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	17-03-2025
Enrollment:	39
Type:	Anticipated

Medical products/devices used

Generic name:	AD Health Sensor Platform 4.0
Registration:	No

Ethics review

Approved WMO

Date:	11-03-2025
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL87421.058.24