Kinetics of extracellular vesicles in hemodialysis

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To assess the kinetics of EVs in standard HD, derived from both in- (BI) and outside (TI) the ECC.

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

Summary

ID

NL-OMON53277

Source
ToetsingOnline

Brief title
EV kinetics study

Condition

- Renal disorders (excl nephropathies)

Synonym
Tissue injury and bio-incompatibility in hemodialysis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bio-incompatibility, Extracellular vesicles, Hemodialysis, Tissue injury

Outcome measures

Primary outcome

Concentration of EVs in peripheral blood (i. e. CD45, CD61, CD62e, CD62p,

CD235, CD62e, CD144, Connexin-43)

Secondary outcome

not applicable

Study description

Background summary

Hemodialysis (HD) is a lifesaving treatment for patients with end-stage kidney disease (ESKD). Yet, apart from beneficial effects, HD has adverse consequences, which, apart from rapid osmolarity and electrolyte shifts, results from the bio-incompatibility (BI) of the extra-corporeal circuit (ECC) and intradialytic hypotension (IDH). While BI arises within the EEC due to the contact between circulating blood cells and the foreign materials of the ECC, IDH-induced tissue injury (TI) originates within the body of the patients. Activated cells can be detected by upregulation of cell surface markers and release of degradation products. Substances which are smaller than the pores of dialyzer-membranes may pass this barrier and, thus, become undetectable in blood.
Various cell types shed small particles upon activation an/or injury, so called extracellular vesicles (EVs). These EVs contain various proteins and are too large to travers dialyzer membranes. Their assessment requires strict pre-analytical precautions. In previous HD research, both pre-analytical circumstances and analytic methods were insufficiently standardized, precluding solid conclusions. Both BI and recurrent IDH, predispose to micro-inflammation and cell activation, which are related to morbidity and mortality. Hence, when analysed properly, the measuring of EVs might be a valuable tool to assess dialysis-induced adverse side-effects, not only in the dialyser but also in the body, which, when occurring repeatedly, may influence survival. Industrial companies may use this information when designing and developing new machines and devices for the benefit of our patients

Study objective

To assess the kinetics of EVs in standard HD, derived from both in- (BI) and

outside (TI) the ECC.

Study design

Prospective observational (pilot) study

Study burden and risks

All measurements of this study are non-invasive and associated with negligible risks. The burden is caused by extra blood pressure measurements and non-invasive blood draws. Blood samples are collected during a regular dialysis treatment (no extra visits) from the extracorporeal circuit (no ,venipunctures). The estimated blood volume (81.3 ml) is not expected to cause a clinically relevant decrease in hemoglobin levels (estimated decrease in Hb level: 0.2 mmol/L). In addition, as a precaution, patients with an Hb level < 6.2 are excluded. This cut-off value is based on the guidelines (target Hb in hemodialysis patients: 6.2-7.4 mmol/l). Furthermore, the hemoglobin level will be checked at the next treatment and, if necessary, the EPO dose will be adjusted.

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 - Stable clinical situation: free of infection, no recent admission - Treatment with HD >3 months - Haemoglobin level >= 6,2 mmol/L - Residual diuresis <200mL/24h - Willing and able to give written informed consent

Exclusion criteria

- Active infection, malignancy, auto-immune disease, or treatment with immunosuppressive medication. - Allergy to polysulfone dialyzers - Life expectancy <3 months due to non-renal disease - No access recirculation

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-11-2023
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	18-09-2023
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL84115.018.23