

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Renal disorders (excl nephropathies)
<b>Study type</b>	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 ECC 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  $\geq 18$  years - Stable clinical situation: free of infection, no recent admission - Treatment with HD  $>3$  months - Haemoglobin level  $\geq 6,2$  mmol/L - Residual diuresis  $<200$  mL/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