Urea monitoring in plasma, sweat and saliva of patients during hemodialysis

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23387

Source
Nationaal Trial Register

Brief title
Umis Studie

Health condition

End stage chronic kidney diseases

Sponsors and support

Primary sponsor: This is investigator initiated research at the Catharina Hospital Eindhoven
Source(s) of monetary or material Support: Catharina Ziekenhuis Eindhoven Catharina Onderzoeksfonds

Intervention

Outcome measures

Primary outcome

The endpoints for the first objective are the correlation coefficients and the bias of urea concentrations in sweat and saliva versus blood, that will be determined with the Bland-Altman method. Possible confounding factors will be analyzed. The endpoint for feasibility (the second objective) is the correspondence of the Kt/V determined in sweat and saliva to

the Kt/V determined in plasma. To analyze the correspondence of Kt/V, Bland Altman analysis will be used to establish bias and variation and to assess this data with the critical difference of plasma Kt/V obtained from experts.

Secondary outcome

Correlation coefficients and the bias of creatinine concentrations in sweat and saliva versus blood.

Study description

Background summary

Rationale:
Hemodialysis supports renal clearance by dialysis of the patients' blood. This is a time consuming treatment with 4 hour cycles, three to five sessions per week. Each patient is monitored using laboratory analysis. Plasma urea concentrations before and after the treatment are used to calculate the dialysis adequacy.
The development of sensors able to measure low volume bio-fluids makes sweat sensing an emerging technology for non-invasive and continuous analyte monitoring. In hemodialysis patients, a sweat sensor that is able to measure the urea concentration could potentially be used to non-invasively and continuously monitor the treatment adequacy. Next to sweat sensing, analysis of the urea concentration in saliva could be an alternative non-invasive method to monitor hemodialysis adequacy.
This study establishes the correlation between urea concentrations determined in blood, sweat and saliva in hemodialysis patients. It should be considered a pilot study to provide insight in the feasibility of sweat and saliva analysis for monitoring hemodialysis adequacy.

Primary objectives:
1. Perform regression and correlation analysis on urea concentrations in sweat/saliva versus blood at the start of hemodialysis (C0), at the end of hemodialysis (Ct) and on the ratio (Ct/C0).
2. Feasibility of sweat and/or saliva analysis to determine the hemodialysis adequacy
Secondary objective:
1. Perform regression and correlation analysis on creatinine concentrations in sweat/saliva versus blood at the start of hemodialysis (C0), at the end of hemodialysis (Ct) and on the ratio (Ct/C0).

Study design: non-therapeutic single-center cohort study (WMO-plichtig)

Study population: 40 hemodialysis patients at the Catharina Hospital Eindhoven

Study objective

There is a relation between urea concentrations in blood, sweat and saliva, such that sweat and saliva can be used to non-invasively and continuously monitor hemodialysis adequacy.

Study design

Two timepoints at one hemodialysis session

Intervention

Sweat, saliva and blood will be obtained twice during one hemodialysis session: one time at the start and the other time at the end of the hemodialysis session.

Contacts

Public
Catharina Ziekenhuis Eindhoven
Sophie Adelaars

040 239 6383
Scientific
Catharina Ziekenhuis Eindhoven
Sophie Adelaars

040 239 6383

Eligibility criteria

Inclusion criteria

- Patient is being treated with hemodialysis in the Catharina Hospital Eindhoven

Exclusion criteria

- <18 years
- Hospitalization for any reason other than hemodialysis treatment
- Patients with an implanted device, such as a defibrillator, neurostimulator, pacemaker, or ECG monitor.
- Patients with a history of epilepsy or seizures.
- Patients who are pregnant.
- Patients that have a known sensitivity or allergy to any used ingredient.

- Over damaged, denuded skin or other recent scar tissue.
- Patients with Cardiac Conditions or with suspected heart problems.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2021
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	26-10-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 51983

Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9831
CCMO	NL77434.100.21
OMON	NL-OMON51983

Study results