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

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Main 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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Observational invasive

Summary

ID

NL-OMON51983

Source
ToetsingOnline

Brief title
Urea-monitoring in Sweat and Saliva (Umis Studie)

Condition

- Nephropathies

Synonym
hemodialysis, Kidney diseases

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Catharina onderzoeksfonds

Intervention

Keyword: hemodialysis, monitoring, sweat, Urea

Outcome measures

Primary outcome

Endpoints:

- Correlation coefficients and bias between urea concentration in plasma, sweat and saliva at the start (C0) and at the end (Ct) of hemodialysis and as a ratio (Ct/C0).

- (Difference between) Kt/V values determined with urea concentrations in plasma, sweat and saliva

- (Statistical difference between) the coefficients of the estimated curves for urea concentrations in saliva versus plasma during hemodialysis

Parameters:

- Urea concentrations in plasma, sweat and saliva at the start (C0) and at the end (Ct) of the hemodialysis

- To calculate the Kt/V: ratio of urea concentrations (Ct/C0), time of hemodialysis (T), intradialytic body weight loss (dBW) and the body weight at the end of dialysis (BW)(formula 1).

- Salivary and plasma urea concentrations at four time points during hemodialysis.

Secondary outcome

Endpoint:

- Correlation coefficients and bias between creatinine concentration in plasma,

sweat and saliva at the start (C0) and at the end (Ct) of hemodialysis and as a ratio (Ct/C0).

- (Statistical difference between) the coefficients of the estimated curves for creatinine concentrations in saliva versus plasma during hemodialysis.

Parameters:

- Creatinine concentrations in plasma, sweat and saliva at the start (C0) and at the end (Ct) of the hemodialysis

- Salivary and plasma creatinine concentration at four time-points for saliva and blood during hemodialysis.

Study description

Background summary

Hemodialysis supports renal clearance by dialysis of the patients* blood. This is a time consuming treatment with 4 hour cycles, up 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.

Study objective

Main 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
3 To obtain more knowledge about the kinetics of salivary urea concentrations during hemodialysis.

Secundary objective:
• Perform regression and correlation analysis on creatinine concentrations in sweat/saliva versus blood at the start of hemodialysis (C0), at the end (Ct) and on the ratio (Ct/C0).
• To obtain more knowledge about the kinetics of salivary creatinine concentrations during hemodialysis.

Study design

This study can be classified as a non-therapeutic single-center cohort study (WMO plichtig).During routine hemodialysis treatment in the hospital, a sweat, saliva and blood sample will be collected at the beginning and the end of the treatment. Two additional saliva and plasma samples will be collected during hemodialysis. The samples are collected during treatment, therefor the study-procedure will not elongate the hospital stay

Study burden and risks

There is no extra risk or burden associated with participation. Sweat stimulation and collection will be done by a validated method that is also used in routine practice. This method is based on pilocarpine iontophoresis with the Macroduct® Advanced Sweat collection system 3700/3710 (CE marked) according to manufacturer*s instructions. During the stimulation of the sweat, the patient might experience a tinkling or slightly irritating feeling on the place of stimulation on the under arm, this should not be painful. There will be four blood draw moments per patient, with 2x 5 tubes and 2x 3 tubes per draw. Saliva collection is non-invasive. The risk and burden for the patients during this study are minimal.

Contacts

Public
Catharina-ziekenhuis

Michelangelolaan 2

Eindhoven 5823 EJ
NL
Scientific
Catharina-ziekenhuis

Michelangelolaan 2
Eindhoven 5823 EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The patient is treated with hemodialysis

Exclusion criteria

- Age below 18 years old
- 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 invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2021
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	12-08-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	29-10-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	02-03-2022
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23387
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL77434.100.21
OMON	NL-OMON23387