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

Gepubliceerd: 26-10-2021 Laatst bijgewerkt: 15-05-2024

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23387

Bron
NTR

Verkorte titel
Umis Studie

Aandoening

End stage chronic kidney diseases

Ondersteuning

Primaire sponsor: This is investigator initiated research at the Catharina Hospital Eindhoven
Overige ondersteuning: Catharina Ziekenhuis Eindhoven
Catharina Onderzoeksfonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

Two timepoints at one hemodialysis session

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Catharina Ziekenhuis Eindhoven
Sophie Adelaars

040 239 6383

Wetenschappelijk

Catharina Ziekenhuis Eindhoven
Sophie Adelaars

040 239 6383

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- <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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-10-2021
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	26-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51983
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten