Ultrafiltration guided by Total Body Electrical Resistance in Patients on Daytime Hemodialysis: A Pilot Study on Feasibility

Published: 04-11-2019
Last updated: 10-04-2024

To evaluate the feasibility of TBER-guided ultrafiltration (UF) in patients on HD, using an end-of-HD TBER score of +2 SD as the optimal target.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47950

Source
ToetsingOnline

Brief title
TBER-guided ultrafiltration

Condition

- Other condition
- Renal disorders (excl nephropathies)

Synonym
Fluid balance, hydration status

Health condition

Afwijkingen in de hydratiestatus van het lichaam ten gevolge van eindstadium nierfalen

Research involving

Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Radboud-Rijnstate promotiefonds

Intervention

Keyword: Bioimpedance, Hemodialysis, Resistance, Ultrafiltration

Outcome measures

Primary outcome

Blood pressure, number of intra- and inter-dialytic events, and quality of life.

Secondary outcome

Number and doses of antihypertensive medication and vena cava diameter.

Study description

Background summary

Cardiovascular morbidity and mortality are high in patients on hemodialysis (HD) and this is partially related to suboptimal fluid balance management due to a lack of accurate tools. During HD, ultrafiltration (UF) is used to remove the excess fluid that has accumulated in the period between two HD*s. The aim of UF should be to remove sufficient fluid to prevent overhydration in the inter-dialytic period, but also to avoid excessive fluid removal that may cause intra-dialytic events such as hypotension and muscle cramps. This is a very delicate balance, not well manageable with currently available tools. To date, fluid management is still based on the dry weight approach, a subjective, composite target depending on a multitude of clinical variables with limited accuracy and specificity in defining optimal hydration. We hypothesize that monitoring of hydration can be improved by measurement of Total Body Electrical Resistance (TBER) to a 50 kHz alternating current, and the use of a recently developed method that defines a personalized, TBER-derived hydration normal range. According to this method a TBER-SD score > +2 reflects dehydration and a SD score < -2 indicates overhydration. We hypothesize that optimal fluid management is achieved with an end-of-HD TBER score of +2 SD. A pilot study is warranted to assess the feasibility of this new approach.

Study objective

To evaluate the feasibility of TBER-guided ultrafiltration (UF) in patients on HD, using an end-of-HD TBER score of +2 SD as the optimal target.

Study design

Pilot study.

Intervention

Serial measurement of TBER during HD by gel electrodes positioned on hand and foot to guide UF towards the predicted, patient-specific, TBER target value of +2 SD at the end of HD.

Study burden and risks

The burden of TBER measurements is nihil. The main burden for participating patients is the time required to keep diaries, answer questionnaires, and to undergo non-invasive diagnostic tests. If necessary, patients may receive prolonged or additional HD sessions. Risks are expected to be not different from patients treated with conventional HD.

Contacts

Public
Rijnstate Ziekenhuis

Wagnerlaan 55
Arhem 6815 AD
NL
Scientific
Rijnstate Ziekenhuis

Wagnerlaan 55
Arhem 6815 AD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age > 18 years
On daytime hemodialysis (HD) for * 6 months
Baseline hydration status classified by total body electrical resistance (TBER):
- Requiring an increase in UF, i.e. post-HD TBER-SD score < +1 SD, or
- Requiring a decrease in UF, i.e. post-HD TBER-SD score > +3 SD
Clinical probability that the patient will be able to complete the trial successfully

Exclusion criteria

Chronic mental illness
Systolic heart failure
Metallic knee prosthesis on measuring side
Amputated limb on measuring side
Paraplegia or hemiplegia on measuring side

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	24
Type:	Anticipated

Medical products/devices used

Generic name:	Bio-electrical impedance analysis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-11-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-08-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL70975.091.19