Exploring characteristics of haemodialysis patients related to successful individual application of bioimpedance to help determine the endpoint of dialysis treatment

Published: 23-10-2018 Last updated: 13-04-2024

The primary objective of this study is to explore characteristics (nutritional status, body composition, and presence of comorbidities) of HD patients related to successful individual application of bio-electrical impedance to determine the endpoint...

Ethical review	Approved WMO
Status	Pending
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational non invasive

Summary

ID

NL-OMON46424

Source ToetsingOnline

Brief title Biolyse

Condition

• Renal disorders (excl nephropathies)

Synonym

End-stage renal disease, kidney disease

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bioimpedance, Dry weight, Haemodialysis

Outcome measures

Primary outcome

The primary endpoint constitutes whether BIA can be successfully used to

determine the endpoint of HD treatment. *Success* is hereby defined as post-HD

normovolemia as assessed by BIA.

Secondary outcome

Secondary parameters include nutritional status, body composition, and the

presence of comorbidities.

Study description

Background summary

Determining the optimal endpoint for haemodialysis treatment is essential to prevent symptoms related to over- or underhydration. Currently, objective measures are lacking. Bioimpedance analysis is deemed a promising tool to aid in the clinical decision-making process, but large interpersonal differences are observed regarding the interpretability of results. Since potential bioimpedance-guided fluid management will be performed on an individual level, it is imperative that results can be interpreted reliably among different patients. The inconsistencies suggest that patient characteristics, which have not yet been identified, may contribute to its successful individual application in clinical practice.

Study objective

The primary objective of this study is to explore characteristics (nutritional status, body composition, and presence of comorbidities) of HD patients related

to successful individual application of bio-electrical impedance to determine the endpoint of dialysis treatment.

Study design

Exploratory single-centre, observational, cross-sectional study.

Study burden and risks

Bioimpedance is a safe and non-invasive technique. Measurements will be performed during two separate routine HD treatments and no other procedures will be performed, which minimises the burden on participants. It is vital that this study is carried out in actual ESRD patients undergoing routine HD as bioimpedance measurements have to be taken during HD sessions. Although participants do not experience direct benefit from participating in this study, they contribute to the body of knowledge regarding endpoint determination of HD treatments.

Contacts

Public Wageningen Universiteit

Stippeneng 4 Wageningen 6708WE NL **Scientific** Wageningen Universiteit

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

ESRD patients undergoing intermittent daytime haemodialysis treatment at Ziekenhuis Gelderse Vallei in Ede Undergoing routine HD treatment for at least three months

Exclusion criteria

Pacemaker	
Metal implants	
Major amputations	
Pregnancy	
Restless legs	
Dementia	

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Prevention	

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2018
Enrollment:	120
Туре:	Anticipated

Ethics review

Approved WMO	
Date:	23-10-2018
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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 CCMO **ID** NL62175.081.17