Improvement of dry-weight in dialysis patients using bioelectrical impedance analysis

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To investigate if determining dry-weight with the assistance of bioelectrical impedance analysis compared to the current practice will result in a better blood pressure control.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON36049

Source
ToetsingOnline

Brief title
Dry-weight determination using BIA

Condition

- Cardiac disorders, signs and symptoms NEC
- Renal disorders (excl nephropathies)

Synonym
Fluid overload dry-weight

Research involving
Human

Sponsors and support

Primary sponsor: Dianet, locatie AMC, Amsterdam
Source(s) of monetary or material Support: Dianet financieert dit zelf

Intervention

Keyword: bioelectrical impedance analysis, dialysis, dry-weight, fluid overload

Outcome measures

Primary outcome

Blood pressure

Secondary outcome

Number of hospital admissions due to fluid overload

Number of additional dialysis sessions due to fluid overload

Number of intradialytic hypotension episodes and/or the number

hypotension-associated dialysis symptoms

Number of antihypertensive drugs

Serum levels of NT-proBNP, albumin and CRP

Cardiovascular related morbidity and mortality

Development of anuria (200 ml/day)

Study description

Background summary

Hydration and volume status are important predictors of outcome in patients with end-stage renal disease on renal replacement therapy. Evaluation of *euvolemia* untill now is, however, severely hampered by the lack of a reliable objective tool that can be used to measure volume status in everyday clinical practice. Multifrequency bioimpedance offers the possibility of evaluating in a simple way at bedside the body composition and hydration of the patient. However, evidence is lacking if introduction of this device for routine use in clinical practice is of benefit for patient outcome.

Study objective

To investigate if determining dry-weight with the assistance of bioelectrical

impedance analysis compared to the current practice will result in a better blood pressure control.

Study design

Prospective multicentre randomised clinical trial. The patients will be randomized in two groups. In group 1 bioelectrical impedance analysis will be leading in the assessment of the dry-weight .In group 2 the assessment of dry-weight will be performed according to the currently used clinical parameters. The patients will be followed for 2 years.

Intervention

Measurement of the body composition using Bio-electrical Impendance Analysis

Study burden and risks

There are no additional risks attached to this study. In both groups the chance exists on the development of dialysis related complications such as hypotensive episodes. These risks are also present without participation in the study. Participation in the study will result in a total extra time investment of the patient of 150 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients must have CKD stage 5 and treatment with hemodialysis or peritoneal dialysis

Exclusion criteria

Heart failure
Expected to receive a living donor transplant within 6 months
Life expectancy less than 6 months
Contraindications for the use of BIA measurements (due to expected measurement errors)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-07-2012
Enrollment:	160

Type: Actual

Medical products/devices used

Generic name: Body Composition Monitor

Registration: Yes - CE intended use

Ethics review

Approved WMO

Application type: First submission

Review commission: METC Amsterdam UMC

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	NL37162.018.11