MRI and volume homeostasis in hemodialysis patients

Published: 25-05-2016
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To investigate the application of magnetic resonance imaging in detecting changes in tissue water content in patients undergoing hemodialysis.

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

Summary

ID

NL-OMON43479

Source
ToetsingOnline

Brief title
MRI in hemodialysis patients

Condition

- Renal disorders (excl nephropathies)

Synonym
dryweight, hemodialysis

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: beurs Maasstadziekenhuis raad van bestuur

Intervention

Keyword: dry weight, hemodialysis, MRI, volume homeostasis

Outcome measures

Primary outcome

Change in water content, expressed as percentage water and change in diffusion

coefficient in brain, liver and calf muscle before and after dialysis.

Secondary outcome

Weight measurement, diameter inferior vena cava

Study description

Background summary

End-stage renal insufficiency requires renal replacement therapy, either a form of dialysis or kidney transplantation. The major difficulty concerning dialysis is maintaining volume homeostasis. Assessment of volume status is mostly based on clinical examination of the patient and the weight at the end of the previous dialysis treatment. Wrong assessment induces either hypervolemia or hypovolemia, both negatively impacting the clinical condition of the patient and residual renal function. More objective measurements such as biochemical markers, inferior vena cava ultrasound and bioimpedance analysis all possess substantial limitations. We hypothesize that magnetic resonance imaging could be an accurate diagnostic tool for assessment of tissue water content and total body volume status.

Study objective

To investigate the application of magnetic resonance imaging in detecting changes in tissue water content in patients undergoing hemodialysis.

Study design

Quasi-experimental observational study

Study burden and risks

The burden for the individual participant consists of undergoing MRI scanning, which could be considered time-consuming and claustrophobic. One MRI session might last up to half an hour to obtain images of brain, liver and calf muscle. Patient claustrophobia is a relative contra-indication for undergoing a MRI

scan. In addition, inferior vena cava ultrasound measurement, weight measurement and bioimpedance analysis will be a substantial part of participation. Since all measurements will be performed before and after one single hemodialysis session, there is no need for additional hospital visits. Potential risks linked to participation are minimal. Each patient will be screened for ferromagnetic implants, pregnancy and claustrophobia through usage of a standardised questionnaire.

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

hemodialysis, stable medical situation, > 3 litres ultrafiltration

Exclusion criteria

contra indication MRI
acute kidney failure

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2016
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	25-05-2016
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL56242.101.16