Validation of Body Composition Monitor (BCM) in pediatric dialysis patients

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Primary Objective: Validation of the Fresenius BCM in pediatric dialysis patients for the assessment of TBW and ECW using dilution techniques as the reference methods.Secondary Objective: Validation of saliva sampling for bromide concentration...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON38668

Source
ToetsingOnline

Brief title
BCM and pediatric dialysis

Condition

- Heart failures
- Nephropathies

Synonym
chronic fluid overload

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: It needs to be determined

Intervention

Keyword: BCM, dialysis, End-stage renal disease, pediatric

Outcome measures

Primary outcome

comparison of TBW and ECW assessment by BCM vs. deuterium and bromide dilution

Secondary outcome

validation of the extracellular water assessment by means of bromide dilution

using saliva samples for bromide concentration measurements vs. blood samples.

Study description

Background summary

Cardiovascular disease (CVD) is the main cause of death in patients with pediatric onset of end-stage renal disease. Chronic overhydration in dialyzed children is an important determinant of cardiac dysfunction and hypertension. In current practice, fluid status is clinically assessed, which is known to be inaccurate, especially in children. Recently, non-invasive assessment of extra- and intracellular water by means of Body Composition Monitor (BCM) has been advocated. BCM assessment of fluid compartments relies on the mathematical modeling of body compartments and has been validated in adults. As the body composition in children differs from that in adults with respect to total and extracellular water, we want to verify if the BCM algorithms are applicable in children.
The gold standards to assess the main body volumes, total body water (TBW) and extracellular water (ECW), are deuterium and sodium bromide dilution, respectively. They are safe and accurate techniques, but unpractical in the clinical setting. BCM is a non-invasive and bedside technique, that can determine TBW and ECW in less than two minutes. It has been validated in healthy subjects and dialyzed adults, but not in pediatric dialysis patients.

Study objective

Primary Objective:
Validation of the Fresenius BCM in pediatric dialysis patients for the assessment of TBW and ECW using dilution techniques as the reference methods.

Secondary Objective:
Validation of saliva sampling for bromide concentration measurement in the bromide dilution technique for ECW estimation, using plasma as the reference method.

Study design

Study participants will undergo TBW and ECW measurements by standardized dilution methods and BCM:
* Deuterium and sodium bromide dilutions:
After an overnight fast subjects are required to drink 0,06 ml/kg of a solution containing deuterium and, after 3 hours, 10 ml of a sodium bromide solution. Both deuterium and sodium bromide are innocuous fluids. Samples of saliva are collected prior to ingestion of the deuterium solution and after 2,3 and 4 hours. Two blood samples of 2 ml each are required: one prior to ingestion of sodium bromide and one 3 hours later.
BCM measurements:
For BCM measurement, the subject is required to remain quiet and recumbent for the duration of the test. Electrodes are applied and body composition measurement is performed in less than 2 min. It is a painless procedure. BCM measurements will be obtained between sodium bromide intake and the last blood sample.
* Additional measurements:
Two further samples of saliva are collected just before the final blood sample to validate the assessment of ECW by bromide concentration in saliva.

Study burden and risks

The burden and risks are linked to the fast, blood sampling, prolongation of duration of hospital visit. The use of bromide and deuterium is safe and adverse effects are not to be expected.
This study will provide important data on the applicability BCM in dialyzed children to monitor fluid balance in a non-invasive and easy way, which is a direct benefit to the quality of care of children on dialysis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

* Age 5-17 years
* Dialyzed patients
* Informed consent parents & patients

Exclusion criteria

* Acute illness (fever)
* Mental retardation
* Children with prosthesis or other fixed devices
* Children who took bromide containing medications (e.g. ipratropium bromide)
* Children with overnight enteral nutrition
* Weight < 15 kg

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-10-2013
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	BCM
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	19-09-2013
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	NL45187.018.13