BIOELECTRICAL-IMPEDANCE ANALYSIS TO IMPROVE ESTIMATES OF CREATININE CLEARANCE IN RENAL TRANSPLANT RECIPIENTS

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

Summary

ID

NL-OMON31959

Source
ToetsingOnline

Brief title
BIAPIN

Condition

- Renal disorders (excl nephropathies)

Synonym
chronic renal failure, kidney transplantation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,apparatuur in bruikleen van fabrikant

Intervention

Keyword: bioelectrical impedance, glomerular filtration, kidney transplantation

Outcome measures

Primary outcome

Estimation of the creatinine clearance using different methods

Secondary outcome

None

Study description

Background summary

The creatinine clearance is commonly accepted as the best parameter to asses the kidney function. There are many different mathematical formulas to make an estimation of the creatinine clearance. Most of them are based on the measurement the serum creatinine concentration. The evaluation and availability of various formulas taken with the fact that none of these formulas is adequate for all patient populations can lead to confusion and misunderstanding in daily practice when estimating kidney function.
In renal transplant recipients formulas that predict creatinine clearance (such as the Cockcroft-Gault) derived from patients with chronic renal failure and standardized against measured creatinine clearance are not accurate.
In these patients the relationship between serum creatinine and creatinine clearance is more variable and dependent on factors (e.g. disease states) that alter muscle mass and muscle catabolic rate.
Preceding research has shown that variables as age, sex, ethnicity, height and weight explain a significant part of the variability of the kidney function.
It*s has been commonly accepted that these variables have a direct influence on kidney function and are used combined with serum creatinine to estimate the creatinine clearance. However these variables are also predictors of skeletal muscle mass, the biggest source of creatinine, the clearance of which is used to estimate the creatinine clearance .
Skeletal muscle mass can be predicted by the use of demographic variables but a more accurate estimation method uses bioelectrical impedance analysis (BIA).
BIA is an easy non-invasive and convenient method to assess a patient*s total

body composition, including muscle mass. By measuring the total body composition an accurate estimation of the muscle mass can be made

Study objective

This study is aimed at the development of a noninvasive method which leads to a more accurate and precise estimation of the creatinine clearance when compared with the Cockroft-Gault, MDRD or Nankivell formulas and taking the 24-hour urine creatinine clearance as a reference in renal transplant recipients.
Using the formulas mentioned above (also see Methods) combined with bio impedance measurements, we hypothesize that bio impedance will prove to have additional value as a predictor of the muscle mass of a patient. This may lead to a better prediction of the creatinine clearance than with currently used methods.

Study design

Observational study

Study burden and risks

participants will have 4 electrodes (2 to hand, 2 to foot) placed for every BIA measurement, after which a read-out takes place. The burden and risks can be considered to be very small.

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

- age 18 years and older
- medical history after renal transplantation carried out in the AMC
- admitted to the renal transplant unit (F5NS) or visiting the out-patient department of the AMC
- collecting 24-hour urine for the routine assessment of renal graft function
- giving written informed consent for participation to this study

Exclusion criteria

None

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2008
Enrollment:	50

Type:	Anticipated

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	NL23029.018.08