Kidney function assessment in geriatric patients

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The objective of this study is to determine the accuracy of the Cockcroft-Gault and the MDRD formula as estimators of GFR in geriatric patients. Some other new methods for daily practice will be investigated as well (see primairy parameters).

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

Summary

ID

NL-OMON33637

Source
ToetsingOnline

Brief title
KAG-study

Condition

- Renal disorders (excl nephropathies)

Synonym
kidney failure, renal failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: assessment, elderly, geriatric, GFR

Outcome measures

Primary outcome

Following referencetest is applied to every participant as the primairy parameter.

· Inutest *single-shot* method, to measure sinistrin clearance, in ml/min.

Next methods are secondary parameters and will be compared with the reference method:

· Cockcroft-Gault formula in ml/min.

· MDRD formula in ml/min/173m²

• MCQ-formula in ml/min

• Virga-formula in ml/min

• Jelliffe-formula in ml/min

• Salazar-Corcoran-formula in ml/min

• Martin-formula in ml/min

• Wright-formula in ml/min

• Larsson-formula in ml/min

• Hoek-formula in ml/min

· Creatinine clearance estimation form 2-hour urine sample, in ml/min.

· Cystatine C plasma concentration, in mg/l

To estimate GFR with the formulas, following variables must be collected :

· Serum creatinine concentration

· Serum ureum concentration

· Serum albumin concentration

· Serum Cystatine C concentration

· Gender

· Race

· Date of birth

· Body Mass Index (BMI)

Secondary outcome

Following participant features will be collected for baseline table:

- primairy diagnosis

- co-morbidities

- drugs used

Study description

Background summary

The estimation of renal function is an important tool for physicians who work with elderly or geriatric patients. Elderly patients have a high incidence of impaired renal function and are prone to adverse drug reactions and acute illness. Within the pharmaco-therapeutic proces, glomerular filtration rate (GFR) estimation can therefore be used as a motivator for drug dose adjustments. Recently new methods for GFR estimation have been introduced for daily clinical practice. Two formulas, the Cockcroft-Gault and the Modification of Diet in Renal Disease (MDRD) formula, have gained a lot more popularity than the old method of plasma creatinine measurement on its own. Besides the plasma creatinine, these formulas are also based on variables such race, age and

weight. Most guidelines, recommend the use of these formulas for GFR estimation, but the evidence is based on validations in adult populations. Only little evidence is known for the accuracy of formulaic GFR estimation in geriatric medicine. Studies who investigated the accuracy of the formulas in geriatric patients, are inconsistent with the use of their reference method and have different outcomes as well.

Study objective

The objective of this study is to determine the accuracy of the Cockcroft-Gault and the MDRD formula as estimators of GFR in geriatric patients. Some other new methods for daily practice will be investigated as well (see primairy parameters).

Study design

To determine the accuracy of different formulas and methods, a comparison with a reference test will be made. Different reference methods for GFR measurement are known, but the inulin clearance is recommended by evidence based guidelines as the golden standard.
In this study, the inuline clearance will be measured by the use of Inutest. Inutest contains the totally passive substance of sinistrin. Sinistrin is an improved version of inulin. Participants will get a injection of sinistrin solution. After the injection, multiple blood samples will be gathered. This procedure will take one day and is done on our geriatric ward. At the same time, GFR will be estimated with the formulas and be compared with the golden standard Inutest.

Study burden and risks

Inutest contains a solution of sinistrin, which is a totally passive fructose for the human body. It is not bonded to plasma proteines and fully cleared by the kidneys. There are no adverse drug reactions or interactions with other drugs known. There is a very small chance of allergic reaction to sinistrin. Participants will get one intraveneus injection of sinistrin and one intraveneus device for multiple blood collection. There will be a 2-hour urine collection gathered with non-invasive methods.

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

Decision-making competence, aged > or = 70, MDRD < or = 60 ml/min, clinical and outward patients, stable clinical condition

Exclusion criteria

Decision-making incompetence;Terminal stadium of disease

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):	10-02-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	25-03-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-05-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-12-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL19442.041.07