Comparison of GFR measurement and GFR estimation with 125I-labelled iothalamate, 51Cr-EDTA, Gd DTPA, and two formulas based on cystatin C and creatinine.

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To compare the accuracy of the measured GFR using bolus 51Cr-EDTA, and Gd DTPA, and estimated GFR using cystatin C and creatinine with the continuous 125I-labelled iothalamate infusion method.

Ethical review	Approved WMO
Status	Pending
Health condition type	Nephropathies
Study type	Observational invasive

Summary

ID

NL-OMON31536

Source
ToetsingOnline

Brief title
Assesment of kidney function in various causes of renal disease

Condition

- Nephropathies

Synonym
kidney disease, renal failure

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: stichting nephron

Intervention

Keyword: 51CR-EDTA, Cystatin C, Gd DTPA, GFR

Outcome measures

Primary outcome

The accuracies of GFR determination using 51Cr-EDTA, Gd-DTPA, cystatin C (using the Hoek-formula) and creatinine (using the MDRD - and Cockcroft and Gault formula) will be compared to continuous 125I-labelled iothalamate/ 131I-labelled hippuran infusion as gold standard.

Secondary outcome

1. Gd-DTPA, cystatin C (using the Hoek-formula) and creatinine (using the MDRD - and Cockcroft and Gault formula) will be compared to 51Cr-EDTA.

2. Subanalysis of these parameters in the four different patients groups.

Study description

Background summary

In patients at risk of developing renal failure, adequate measurement of glomerular filtration rate (GFR) is of utmost importance. In case of deterioration of renal function, treatment if possible of the underlying cause must be initiated without delay; treatment in an early stage of kidney failure is most effective.
Many attempts have been made to find an ideal method to determine GFR. GFR can be measured or can be calculated. So far, inuline clearance or infusion with radio-active substances are considered gold standard, but they are. expensive and cumbersome. There is a need for easier and cheaper methods.
Gd DTPA is a newly developed method to determine renal function after the a single injection with gadolineum. Cystatin C is a relatively new endogenous

marker to asses renal function. If Gd-DTPA and/or Cystatin C show a good correlation with the 'gold standard' using 125I-labelled iothalamate in a continuous infusion method or bolus infusion of 51-chromium-ethylenediaminetetraacetic acid (51Cr-EDTA), they could replace these methods in the future.

Study objective

To compare the accuracy of the measured GFR using bolus 51Cr-EDTA, and Gd DTPA, and estimated GFR using cystatin C and creatinine with the continuous 125I-labelled iothalamate infusion method.

Study design

Crossectional study in patients at risk of developing renal failure. GFR will be determined using 125I-labeled iothalamate, 51Cr-EDTA, Gd DTPA, a cystatin C-based formula and a creatinine-based formula.

Study burden and risks

The persons participating in the study have to come to the hospital for one extra day. On this day they will undergo several investigations which in total will last about 5 hours. They will be given an intravenous catheter in the right and left ante-cubital vein through which gadolineum and radio-active chromium will be administered and blood will be drawn. Allergic reactions after adminstration of gadolineum and chromium have been reported (rare). After the administration of gadolineum in a 20x higher dose, nephrogenic systemic fibrosis has been reported, and only in patients with end-stage renal disease.

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

- > 18 years
-Patients have to belong to one of the following categories: those with Fabry disease, those with HIV, those with a status after renal transplantation or those that are willing to donate a kidney.
-Patients (from the outpatient clinic of metabolic diseases and infectious diseases) in whom renal function was measured with 125I-labeled iothalamate/131I-labeled hippuran GFR in the previous year (i.e patients with Fabry disease or with HIV).
-Stable renal function as estimated by a stable serum creatinine during the previous year.

Exclusion criteria

-Female patients who are pregnant or unwilling to use adequate contraception during the study.
-A known allergy to either 51Cr-EDTA or gadolineum DTPA (Magnevist).

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):	01-05-2008
Enrollment:	60
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	NL20756.018.08