Feasibility of laboratory monitoring in community pharmacy by point of care testing of creatinine and potassium in ambulatory elderly at risk for impaired renal function

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Feasibility of laboratory monitoring in community pharmacies by Point-Of-Care testing creatinine and potassium in ambulatory elderly at risk for impaired renal function.

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

Summary

ID

NL-OMON34595

Source
ToetsingOnline

Brief title
Testing renal function in community pharmacy

Condition

- Renal disorders (excl nephropathies)

Synonym
Impaired renal function; Chronic Kidney Disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Abbott Diagnostics Nederland divisie POCT: stelt materialen ter beschikking,Kring-apotheek BV draagt bij aan promotie formatieplaats,Kring-apotheek BV en KNMP

Intervention

Keyword: impaired renal function, laboratory monitoring, point of care

Outcome measures

Primary outcome

Feasibility of laboratory monitoring in community pharmacies by Point-Of-Care testing creatinine and potassium in ambulatory elderly at risk for impaired renal function. Evaluation of experiences of the patients, pharmacy employees and GPs by a questionnaire.

Secondary outcome

1. Number of approved pharmacist advices by the total number of pharmacist advices after POC-testing

2. Number of subjects with POC-testing by total number of included subjects

3. Number of subjects with impaired renal function (< 50 ml/min/1.73 m2) by the total number of included subjects

4. Number of subjects with abnormal potassium levels by the total number of included subjects. Hyperkalemia: > 6.0 mmol/l; normal: 3.5 - 5.0 mmol/l; hypokalemia: < 3.0 mmol/l.

5. Number of subjects exposed to a second POC-test by number of subjects with POC-testing

Study description

Background summary

The prevalence of impaired renal function is high in the Netherlands: 4-5%. Important risk factors for impaired renal function are age, diabetes, and cardiovascular diseases. In patients with impaired renal function it is sometimes necessary to adjust the therapy to prevent medication errors. Without adjustment, the drug can accumulate in patients at risk and adverse drug reactions will become manifest. In a study done by Van Dijk et al. dose adjustments did not take place in 40% of the patients with impaired renal function at disposal. In the HARM-study 5.6% of the acute hospital admissions were related to medication and half of the admissions were potentially preventable. Impaired renal function was one of the potential risk factors for medication-related hospital admissions. In addition, these preventable hospital admissions harm individual patients and give high costs, which are an unnecessary burden for community. According to the Dutch medical guidelines for diabetes, and cardiovascular diseases, at least once a year renal function has to be monitored, and if necessary also potassium. It is unknown how often general practitioners monitor renal function or potassium in these patients and how often therapy adjustments were performed in the Netherlands. The pharmacist has a legal treatment responsibility for the patient and therefore information about laboratory monitoring is essential to assess this responsibility.

Study objective

Feasibility of laboratory monitoring in community pharmacies by Point-Of-Care testing creatinine and potassium in ambulatory elderly at risk for impaired renal function.

Study design

Feasibility study:
The pharmacist selects the population at risk for impaired renal function in the pharmacy computer system for each GP based on the criteria for inclusion. The GP identify subjects without an actual renal function. An informed consent letter is send to subjects with unknown renal function to achieve a population with consent. Eligible subjects with consent are flagged in the computer system for identification when visiting the pharmacy. If 25-50% of the MDRDs is unknown, we expect 1-2 patients per week for POC-testing for each GP. Including subjects for POC-testing is stopped after reaching the desired number of subjects (4-8 weeks). When one of the subjects visits the pharmacy in the study period, the subject is asked to participate for POC-testing of creatinine and potassium in the pharmacy.
For each pharmacy a pharmacist and technician will be trained by the UMC

Utrecht. The trained pharmacist or technician analyses creatinine and potassium in a blood sample from a finger puncture with the Abbott I-stat 1 in a separate consulting room. MDRD is calculated with the equation provided by National Kidney Foundation (http://www.kidney.org/professionals/kdoqi/gfr_calculator.cfm) If the MDRD is below the critical value for a drug according the Dutch clinical guideline for impaired renal function of the KNMP, the pharmacist assesses alerts associated with impaired renal function for relevant drugs and will give a therapy advice. All data are registered in the medical record and on the research document. The pharmacist proposes therapy adjustments directly to GP and communicates these with the subject. If direct communication with the GP is not possible, the subject is send home and phoned by either the pharmacist or the GP as soon as possible.
One week after intervention subjects will be send a questionnaire. After the study is stopped, a questionnaire will be send to the pharmacy and GPs.

Intervention

Subjects visiting the pharmacy will be asked to participate for POC-testing creatinine and potassium by use of a finger prick. POC-testing is only done when the MDRD is not known at the GP*s.
Based on the MDRD the pharmacist will give a therapy advice: dose adjustment, frequency adjustment, stopping the drug or changing the drug. In concordance with the patient and the GP, the pharmacist will effectuate the advice.

Study burden and risks

One finger prick per patient, if the MDRD is near a critical value (+/- 10%), the POC-test will be repeated after 7 days. After the intervention the patients will receive a questionnaire that will take 10 minutes to fill in. Further constraint and risk for the patient will be minimal and justifies this study in patients of which the MDRD should be known. Without knowing the MDRD the pharmacist can not assess alerts for drugs related to impaired renal function and show his professional responsibility. Taking a blood sample with the finger prick method is part of routine in medical practice and can not be considered as an additional risk.

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

Eldery 70 years old or older, under treatment by their own GP. Users on maintenance therapy for diabetis and/or cardiovascular diseases for which therapy adjustments are necessary in case of impaired renal function
ambulatory

Exclusion criteria

MDRD =< 10 ml/min

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-02-2011
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	28-12-2010
Application type:	First submission
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	NL32180.041.10