Fluctuation of the renal function after discharge from hospital and its effects on drug dosing in elderly patients.

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

Summary

ID

NL-OMON43767

Source
ToetsingOnline

Brief title
Fluctuation of the renal function in elderly patients.

Condition

- Renal disorders (excl nephropathies)

Synonym
kidney function, Renal function

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (KNMP);afdeling geriatrie;afdeling klinische chemie;ZANOB

(ziekenhuisapotheek)

Intervention

Keyword: elderly, fluctuation, MDRD, renal function

Outcome measures

Primary outcome

The main study parameter is the estimated glomerular filtration rate (eGFR).

The main endpoint is: 1) What percentage of patients show improved, deteriorated and unchanged renal function at 14 days after discharge from hospital compared to the renal function at discharge? Renal function will be classified according the categories, which are defined in relation to drug management.

Secondary outcome

Other important endpoints are:

1) What percentage of patients show improved, deteriorated and unchanged renal function at 2 months after discharge from hospital compared to the renal function at discharge?

2) Percentage of patients whose actual medications are incorrect according to the Dutch guidelines in relation to their renal function at 14 days and 2 months after discharge.

3) Percentage of patients in whom fluctuation of the renal function would have required dose adaptation of a hypothetical selection of drugs at 14 days and 2 months after discharge.

Study description

Background summary

Chronic kidney disease (CKD) is associated with a higher mortality rate, as well as an increased risk of cardiovascular events and morbidity. Impairment of renal function is common in elderly patients, and their glomerular filtration rate (GFR) should be taken into account when prescribing renally excreted drugs. Dose adjustment of or refraining from renally excreted drugs often take place categorically. In the hospital care setting the renal function may fluctuate so much that the renal function group and therefore the recommended dose, may change easily within a few days. The fluctuation of renal function after discharge from hospital is unknown.

Study objective

The aim of this study is to identify the degree and direction of fluctuation from one to another renal function group within 2 months after discharge from hospital. In addition, prevalence of adaptations of the prescribed drugs that should result from the change in renal function within 2 months after discharge is determined according to the current Dutch guidelines for the patient*s actual medication and a hypothetical selection of most frequently prescribed drugs in elderly patients that require dose adaptation in patients with renal impairment. Risk factors which might lead to increased risk for incorrectly prescribed drugs are also identified and analysed.

Study design

A prospective observational study.

Study burden and risks

At discharge, 14 days and 2 months after discharge from hospital a blood sample will be needed to measure the serum creatinine value. The measurement of creatinine at discharge is almost always usual care. The additional burden for the patient consists of two serum creatinine measurements after discharge of which some are part of usual care. Patients might benefit from participating in this study because additionally measured renal functions will be reported to the general practitioner and/or geriatric physician, who then can adapt the medication of the patient to the renal function reported in an earlier stage than usual care nowadays.The benefits for healthcare professionals comprise of confirmation or adjustment of current recommendations for monitoring renal function after discharge from hospital.

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 >= 70 years,
renal function < 60 ml/min/1.73m2

Exclusion criteria

Patients on dialysis
Patients in their terminal phase

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-01-2013
Enrollment:	129
Type:	Actual

Ethics review

Approved WMO Date:	29-10-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	11-02-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	30-09-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	07-02-2014
Application type:	Amendment
Review commission:	METOPP: Medisch Ethische Toetsing Onderzoek bij Patienten en Proefpersonen (Tilburg)

Approved WMO

Date:	01-06-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL41187.028.12