Effects of Self-monitoring on Outcome of Chronic Kidney Disease

Published: 24-06-2010
Last updated: 04-05-2024

The overall aim of the project is to improve health outcomes and autonomy of CKD patients by testing a self-management care model regarding hypertension control. Furthermore, this study will investigate the impeding and facilitating factors for...

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

Summary

ID

NL-OMON38345

Source
ToetsingOnline

Brief title
ESMO

Condition

- Renal disorders (excl nephropathies)

Synonym
Chronic Kidney Disease (CKD), Kidney Disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw,Nierstichting Nederland

Intervention

Keyword: Chronic Kidney Disease, Hypertension, Psychological factors, Self-management

Outcome measures

Primary outcome

Changes in sodium intake and changes in blood pressure.

Secondary outcome

Renal function (creatinine clearance), proteinuria, albuminuria, urinemarkers

for tubulo-interstiele damage (KIM-1, NGAL en UMOD), antihypertensive

medication and psychological outcome measures.

Study description

Background summary

In the Netherlands an estimated 750.000 patients suffer from CKD, with a kidney function of less than 60%, and it can be expected that this number will increase significantly in the forthcoming decades. A typical characteristic of this patient population is the high level of co-morbidity: Hypertension is the most frequent complication of CKD. For CKD-patients blood pressure control is not only vital for decreasing cardiovascular risk; but also for the decrease of proteinuria in the urine. It is possible that all of this slows down progression of CKD and subsequently reliance on renal replacement therapy may be postponed. Unfortunately, adequate blood pressure control seems hard to achieve. CKD patients generally have two treatment options to control their blood pressure: pharmacological treatment and reducing salt intake.
Regarding the salt-intake, this is hard to achieve due to salt *hidden* in prepared meals and is not added by the patients themselves. In usual care, CKD patients collect urine for 24 hours and return it to the laboratory. Usually, they get the results days (or sometimes even months) later during their next doctor*s appointment.
The current procedure to measure salt intake is inefficient and lacks immediate feedback. Recently, innovative Lab-on-a-Chip technology is being developed that is also applicable for self-monitoring of sodium levels in 24 hours urine.
Self-monitoring is a vital element of self-manage¬ment and the last couple of years self-management is becoming increasingly important. Several studies have shown that self-management increases treatment results and enhances

psychological well-being of patients. The interventions that are most effective for long-term adherence are complex and combines self-monitoring with information, psychological therapy, counseling and feedback. However, little is known about self-management in patients with Chronic Kidney Disease.

Study objective

The overall aim of the project is to improve health outcomes and autonomy of CKD patients by testing a self-management care model regarding hypertension control. Furthermore, this study will investigate the impeding and facilitating factors for implementation of self-management and provide knowledge about the attitude and wishes regarding self-management of the patients and health care workers.

Study design

It is an open randomized controlled trial, in which 150 CKD patients in stage III with hypertension are randomly assigned to either the control condition or intervention condition. After the intervention two follow-up measurements (at 3 and 6 months after the start of the intervention groups) will take place.
In the preparation phase focusgroup interviews will be conducted with CKD patients and health care workers for tine-tuning the intervention. We strive for 4 focusgroups with approximately 8 CKD patients and 4 focusgroups with approximately 8 health care workers.
Before including patients for the RCT, we will pilottest the intervention in 15 CKD patients.

Intervention

The intervention group receives (besides the care as usual) a self-management care model consisting of; self-monitoring sodium intake, keeping dietary diaries, receiving feedback, two motivational interviews and, if necessary, tailored self-management modules

Study burden and risks

There are no risks attached to the study and the participating CKD patients are older than 18 years and mentally competent. The total extent of the study for each individual participant will be 6 months.
The total burden for the control group will be: protocolled instruction for bloodpressure and sodium intake, three times filling out a questionnaire and once an additional visiting the hospital (including drawing blood) and three times handing in 24 hours urine).
The total burden for the intervention group will be: protocolled instruction for bloodpressure and sodium intake, three times filling out a questionnaire and three times additional visiting the hospital (including drawing blood and

hand in 24 hours urine, and two motivational interview conversations), collecting 24-hour urine, home measuring bloodpressure and sodium, filling in nutrition diaries, tailored behavior modules if requested by the patient.

Contacts

Public
Leids Universitair Medisch Centrum

Wassenaarseweg 52
Leiden 2333 AK
NL
Scientific
Leids Universitair Medisch Centrum

Wassenaarseweg 52
Leiden 2333 AK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Informed Consent
- Treated by an internist
- Age above 18 years
- Chronic kidney disease with a creatinin clearance of 20 ml/min/1.73m2 or above
- a recent blood pressure higher than 135/85 mmHg or use of antihypertensive medication (at least 1 RAAS inhibitor)
- Proteinuria above 0,2 g/L or above 0,3 g/24 u

- Last 2 urine sodium measurements higher than 120 mmol/24 uur
- Speaking fluently Dutch

Exclusion criteria

- Blood pressure above 180/100 mmHg or below 125/75 mmHg
- Diabetes Mellitus Type I patients
- Renal transplant less than one year ago
- Acute renal failure
- Rapidly decrease of kidney function (decrease more than 6ml/min/1.73m2 in last year)
- A myocard infarction or cerebrovasculair accident less then 6 months ago
- Malignancy less than five years before inclusion (other than basocellular or squamous cell carcinoma of the skin)
- Participating in other clinical trials requiring the use of study medication

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2010
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	Lab-on-a-chip (sodium measurement device)
Registration:	No

Ethics review

Approved WMO Date:	24-06-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	31-01-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL31970.058.10