Effects of Selfmonitoring on Outcome of Chronic Kidney Disease.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27687

Source
NTR

Brief title
ESMO

Health condition

hypertension, kidney, renovascular, self-management, psychological factors

bloeddruk, nieren, zelfmanagement, psyologische factoren

Sponsors and support

Primary sponsor: Hans Mak Instituut and LUMC
Source(s) of monetary or material Support: ZonMW
Nierstichting Nederland

Intervention

Outcome measures

Primary outcome

1. Changes in sodium intake;

2. Changes in blood pressure.

Secondary outcome

1. Creatinine clearance;

2. Proteinuria/albuminuria;

3. Antihypertensive medication;

4. Psychological outcome measures.

Study description

Background summary

The purpose of the current study is to develop, test, and evaluate a self-management care model regarding CKD patients' salt intake in order to enhance health outcomes and autonomy. For this purpose, a multicenter open randomized controlled trial will be conducted. We will randomize 150 CKD patients having a systolic blood pressure above the target value of 140 mm Hg despite antihypertensive treatment to one of the two study conditions for three months:

1. A control condition in which patients receive care as usual and the possibility to home blood pressure measurement (HBPM);

2. An intervention condition in which above this patients self-measure their sodium levels and keep a diary about their salt intake. This is embedded in a nurse-led self-management approach in which patients receive motivational interviewing to set and obtain appropriate goals. Furthermore, tailored behavioral modules will be available.

At the end of the study we will analyze baseline and follow-up data (3 months and 6 months) to determine whether the intervention condition was superior to the usual care condition regarding primary and secondary outcomes. In this study, we will not only reveal potential effects of the intervention: In the preparation and evaluation process in-depth knowledge will be obtained about patients' CKD beliefs, needs and self-perceived skills regarding self-management and how these compare to attitudes of health care workers. Finally, we will develop a set of recommendations about implementation of self-management for CKD patients.

Study objective

The intervention, optimal selfmanagement conditions for applying to saltrestriction, improves treatment of hypertension in patients with chronic kidney disease.

Study design

1st year: Literature study, focus group interviews, fine tuning design, training motivational interviewing, preparing RCT, pilot logistics, fine-tuning design, finalizing baseline questionnaire;

2nd year: Recruitment of patients, recording baseline data, start intervention;

3rd year: Follow up measures (at 3 months and 6 months), start analyzing data;

4rd year: Analyzing data and reporting findings.

Intervention

Two-arm multicenter open randomized controlled trial. Intervention period of 3 months, follow-up 6 months.

Control and intervention group: All patients are informed about a sodium (salt) restricted diet (< 5 grams salt/day) and instructed how to achieve this. All patients are instructed in home blood pressure measurement and provided with a validated blood pressure measurement device.

Intervention group: In addition to the general procedure, patients in the intervention group receive instructions and materials for self monitoring of the sodium intake. This is established by measuring sodium in their 24 hour urine (Medimate Multireader) and by monitoring their salt intake by dietary diaries. In addition to this they receive nurse-led self-regulation assistance.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age at least 18 years;

2. Creatinin clearance between 90 and 20 ml/min/1.73m2;

3. Systolic bloodpressure higher than 135/85 mm Hg or a normal bloodpressure with antihypertensive treatment (at least 1 RAAS blockade);

4. Command of the Dutch language.
5. Proteinuria > 0.2 g/L or 0.3 g/24 h;
6. Last two sodium measurements > 120 mmol/24 h.

A creatinine clearance of > 90 ml/min/1.73m2 is allowed if patients are treated for their kidney disease by an internist. The new criterion is ‘a creatinine clearance > 20 ml/min/1.73 m2’ (instead of ‘creatinine clearance between 90 and 20 ml/min/1.73m2’).

Exclusion criteria

1. Having undergone renal transplantation < 1 year ago
2. Acute renal failure;

3. Diabetes type 1;

5. Rapidly progressive glomerulonephritis;

6. Malignancy less than 5 years before inclusion;

7. A cardiovascular event less than 6 months before inclusion;

8. Participation in other clinical trials in which using medicine is part of the trial procedures;

9. Blood pressure higher than 180/100 mmHg;

10. Blood pressure lower than 125/75 mmHg.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2011
Enrollment:	150
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-05-2011
Application type:	First submission

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
NTR-new	NL2777
NTR-old	NTR2917
Other	ZonMw : 300020016
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A