

# Shared care for patients with chronic kidney disease in nephrology and general practice.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20375

### Source

NTR

### Brief title

SHARING

### Health condition

1. Chronic kidney disease;
2. Diabetes mellitus;
3. Hypertension;

(NLD: verminderde nierfunctie, diabetes mellitus, hypertensie).

## Sponsors and support

**Primary sponsor:** Department of General Practice  
Radboud University Medical Center Nijmegen (UMCN)  
Department of Nephrology, Radboud University Medical Center Nijmegen

**Source(s) of monetary or material Support:** Dutch Kidney Foundation (Nierstichting Nederland).

## Intervention

## Outcome measures

### Primary outcome

A blood pressure below 130/80 mmHg or decline in blood pressure of 5 mm Hg.

### Secondary outcome

Patients with hypertension: BMI, stop smoking, course of eGFR, lipids, proteinuria, SCORE riskscore

Patients with diabetes mellitus: BMI, stop smoking, course of eGFR, proteinuria, glyHb, fasting bloodglucose, lipids, UKPDS riskscore.

## Study description

### Background summary

A randomized controlled trial will be performed: 9 GP practices will be randomised to control or intervention. Patients with hypertension and/or diabetes mellitus with an estimated glomerular filtration rate  $< 60$  ml/min/1.73 m<sup>2</sup> (MDRD) will be included in the study with a minimum of 20 and a maximum of 28 patients per practice.

The patients in intervention practices will be monitored:

1. Cardiovascular risk (smoking, blood pressure, cardiovascular co-morbidity);
2. Laboratory: creatinine, ureum, sodium, potassium, calcium, phosphate, Hb, MCV, lipids, fasting glucose, glyHb;
3. Urine: albumin, protein, creatinine;
4. Important co morbidity;
5. Medication;
6. UKPDS or SCORE riskengine score.

After 12 months this monitoring will be repeated.

The intervention patients will be treated by GP and practice nurse according to a shared care model. Patients with a GFR  $< 30$  ml/min/1.73 m<sup>2</sup> or a GFR between 30 – 60 GFR /min/1.73 m<sup>2</sup> and proteinuria will be presented to a nephrologist by web based consultation.

In control practices of the NMP project patients will receive usual care (according to the diabetes- and cardiovascular risk-guidelines of the Dutch College of General Practitioners).

### **Study objective**

The hypothesis is that patients with chronic kidney disease will meet treating goals better when they are treated in a shared care model by a general practitioner, a practice nurse and with online consultation of a nephrologist.

### **Study design**

Blood sample and blood pressure when included (baseline) and after 12 months.

### **Intervention**

In intervention practices patients will be treated conform a shared care model by a practice nurse, a GP and a nephrologist. A treatment protocol and web based consultation will be part of this shared care model.

Goals are optimal management of cardiovascular risk.

## **Contacts**

### **Public**

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## **Eligibility criteria**

## Inclusion criteria

Patients with hypertension and/or diabetes mellitus with an estimated glomerular filtration rate < 60 ml/min/1.73 m<sup>2</sup> (MDRD).

## Exclusion criteria

1. Patients with serious medical or psychiatric conditions or drug or alcohol abuse;
2. patients under specialist care for chronic kidney disease in the last year;
3. analphabetism or not being able to read/understand Dutch language (including cognitive disorders);
4. participation in another intervention trial within 30 days before the start of the study.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2008
Enrollment:	225
Type:	Anticipated

## Ethics review

Positive opinion

Date: 25-11-2007  
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 NL1105

NTR-old NTR1140

Other Department of General Practice, Nijmegen : PV 35 (dutch kidney foundation)

ISRCTN ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A