

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

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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.

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestart       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20375

### Bron

Nationaal Trial Register

### Verkorte titel

SHARING

### Aandoening

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

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

### Ondersteuning

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

**Overige ondersteuning:** Dutch Kidney Foundation (Nierstichting Nederland).

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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

## Toelichting onderzoek

### Achtergrond van het onderzoek

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).

## **Doel van het onderzoek**

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.

## **Onderzoeksopzet**

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

## **Onderzoeksproduct en/of interventie**

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.

## **Contactpersonen**

### **Publiek**

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### **Wetenschappelijk**

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

## Onderzoeksopzet

### Opzet

|                  |                         |
|------------------|-------------------------|
| Type:            | Interventie onderzoek   |
| Onderzoeksmodel: | Parallel                |
| Toewijzing:      | Gerandomiseerd          |
| Blinding:        | Open / niet geblindeerd |
| Controle:        | Actieve controle groep  |

### Deelname

|                         |                      |
|-------------------------|----------------------|
| Nederland               |                      |
| Status:                 | Werving gestart      |
| (Verwachte) startdatum: | 01-04-2008           |
| Aantal proefpersonen:   | 225                  |
| Type:                   | Verwachte startdatum |

## Ethische beoordeling

Positief advies

Datum: 25-11-2007

Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|----------|----|
|----------|----|

|         |        |
|---------|--------|
| NTR-new | NL1105 |
|---------|--------|

|         |         |
|---------|---------|
| NTR-old | NTR1140 |
|---------|---------|

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

|        |                                    |
|--------|------------------------------------|
| ISRCTN | ISRCTN wordt niet meer aangevraagd |
|--------|------------------------------------|

## Resultaten

### Samenvatting resultaten

N/A