Prevention of cardiovascular disease and progression of renal failure in patients with chronic renal insufficiency: implementation of maximal endothelial protection with the aid of nurse practitioners. A randomized multi-center study.

Gepubliceerd: 26-10-2004 Laatst bijgewerkt: 18-08-2022

Does intensive multifactorial coaching of patients with chronic renal insufficiency by nurse practitioners result in a reduction in cardiovascular events, cardiovascular mortality, all cause mortality and change in decline of renal function.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25012

Bron
NTR

Verkorte titel
MASTERPLAN (Multifactorial Approach and Superior Treatment Efficacy in

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Assessment of cardiovascular morbidity (comprised of myocardial infarction, stroke and all

vascular interventions, including amputation of an extremity due to vascular insufficiency);
2. Cardiovascular mortality;
3. All cause mortality.

Toelichting onderzoek

Achtergrond van het onderzoek

A multicenter randomized clinical trial will be performed to study whether intensive medical care delivered by a nurse practitioner and a nephrologist will reduce cardiovascular risk compared to care provided by the nephrologist alone. Eight hundred patients will be randomized to physician care or nurse practitioner support to detect a reduction of 50% in cardiovascular events, based on a power of 80%, a two-sided alpha of 0.05.
For all patients the same set of guidelines and treatment goals apply. Both groups will receive treatment according to current guidelines and have access to specific cardioprotective medication. Nurse practitioners will intensify therapy by promoting lifestyle intervention, and meticulous implementation of relevant guidelines.
Patients will be followed for five years after baseline. Primary endpoints are all cause mortality, cardiovascular morbidity and cardiovascular mortality. Secondary endpoints are decline of renal function, change in markers of vascular damage and quality of life.

Doel van het onderzoek

Does intensive multifactorial coaching of patients with chronic renal insufficiency by nurse practitioners result in a reduction in cardiovascular events, cardiovascular mortality, all cause mortality and change in decline of renal function.

Onderzoeksproduct en/of interventie

Bloodpressure Standard : ACE-inhibitor or AII-antagonist (irbesartan)
Target: < 130/85 mmHg
Target: < 125/75 mmHg with proteïnuria > 1 g/dag.

Proteïnuria Intensify antihypertensive therapy
Target: < 0.5 g/dag.
Dyslipidemia Standard: atorvastatine 10 mg
Target : LDL< 2.59 mmol/l.

Anemia Hb < 6.8 mmol/l: start darbepoietin alfa, treat iron deficiency
Hyperhomocysteinemia Standard folicacid 5 mg/dag
Thrombocyteaggregation Acetyl salicylic acid 80 mg/dag unless contra-indicated
Diabetes mellitus Target : GlyHb < 7%
Target: nuchtere glucose < 7.0 mmol/l
Target: niet-nuchtere glucose < 10.0 mmol/l.

Calcium-Phosphate Standard: alfacalcidol 0,25 µg/dag with clearance < 50 ml/min
Target: Phosphate < 1.8 mmol/l and calcium 2.40- 2.60 mmol/l
Target: PTH 1 – 3 x normal
Lifestyle Standard: education about healthy nutrition by a qualified dietician
Target: optimal bodyweight
Standard: optimising physical activity to the level required by dutch guidelines
Standard in case of smoking: stop smoking intervention.

Contactpersonen

Publiek

University Medical Center Utrecht (UMCU),
Department of Nephrology, room F03-226
P.O. Box 85500
Arjan Zuilen, van
Utrecht 3508 GA
The Netherlands
+31 (0)30 2509768

Wetenschappelijk

University Medical Center Utrecht (UMCU),
Department of Nephrology, room F03-226
P.O. Box 85500
Arjan Zuilen, van
Utrecht 3508 GA
The Netherlands
+31 (0)30 2509768

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients are eligible for inclusion when they fulfill the following criteria:
1. The subject is at least 18 years old;
2. The subject is diagnosed with CKD with a creatinine clearance estimated by the Cockcroft-Gault equation between 20 and 70 ml/min;
3. The subject is able and willing to provide written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Also none of the exclusion criteria can be present. The following conditions are considered exclusion criteria:
1. A renal transplant less than a year before inclusion;
2. Acute renal failure or rapidly progressive glomerulonephritis established by the treating physician;
3. Any malignancy less than five years before inclusion other than basocellular or squamous cell carcinoma of the skin;
4. Participation in other clinical trials requiring the use of study medication.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	21-04-2004
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-10-2004
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	NL1
NTR-old	NTR22
Ander register	: 2003B261
ISRCTN	ISRCTN73187232

Resultaten

Samenvatting resultaten
N/A