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.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25012

Source
NTR

Brief title
MASTERPLAN (Multifactorial Approach and Superior Treatment Efficacy in

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Decline in renal function, this will be established by annual measurement of creatinine clearance by 24-hour urine measurements;
2. Quality of life, will be assessed using a validated questionnaire;
3. Markers of vascular damage: aortic pulse wave velocity, carotid intimal media thickness and the ankle-brachial index.

Study description

Background summary

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.

Study objective

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-04-2004
Enrollment:	800
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-10-2004
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	NL1
NTR-old	NTR22
Other	: 2003B261
ISRCTN	ISRCTN73187232

Study results

Summary results
N/A