

Multifactorial Approach and Superior Treatment Efficacy in Renal Patients with the Aid of Nurse practitioners

Submission date
16/05/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date
16/05/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
09/05/2016

Condition category
Urological and Genital Diseases

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

2003B261; NTR22

Study information

Scientific Title

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 randomised multi-centre study

Acronym

MASTERPLAN

Study objectives

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?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee

Primary study design

Interventional

Study design

Multicentre randomised active-controlled parallel group trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Chronic renal insufficiency, renal transplant, cardiovascular disease

Interventions

After the baseline evaluation, the patient will be randomised to either nurse practitioner care or physician care. To all patients the same set of guidelines and treatment goals, shown below, apply. Both patients and physicians are provided with information about the beneficial effects of multifactorial risk factor management regardless of treatment allocation. In the intervention group nurse practitioners, supervised by a qualified nephrologist, will actively pursue lifestyle intervention (physical exercise, nutritional counseling, weight reduction and smoking cessation), the use of specified cardioprotective medication and the implementation of current guidelines. Physician care comprises 'usual care' and conforms to the guidelines below.

Targets and guidelines:

1. Blood pressure:

Standard: ACE-inhibitor or All-antagonist (irbesartan)

Target: less than 130/85 mmHg (less than 125/75 mmHg with proteinuria greater than 1 g/day)

2. Proteinuria intensify anti-hypertensive therapy

Target: less than 0.5 g/dag

3. Dyslipidaemia:

Standard: atorvastatine 10 mg

Target: Low Density Lipoprotein (LDL) cholesterol less than 2.59 mmol/l

4. Anaemia Hb less than 6.8 mmol/l: Start darbepoietin alfa, treat iron deficiency
5. Hyperhomocysteinemia: Standard folic acid 5 mg/dag
6. Thrombocyte aggregation: Acetylsalicylic acid 80 mg/dag unless contra-indicated
7. Diabetes mellitus:
Target: HbA1c less than 7% (preprandial glucose less than 7.0 mmol/l, postprandial glucose less than 10.0 mmol/l)
8. Calcium-Phosphate:
Standard: alfacalcidol 0.25 µg/dag with clearance less than 50 ml/min
Target: Phosphate less than 1.8 mmol/l and calcium 2.40 - 2.60 mmol/l (parathyroid hormone (PTH) 1 - 3 x normal)
9. 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

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

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

Key secondary outcome(s)

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

Completion date

21/04/2009

Eligibility

Key inclusion criteria

1. The subject is at least 18 years old
2. The subject is diagnosed with chronic kidney disease (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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

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

Date of first enrolment

21/04/2004

Date of final enrolment

21/04/2009

Locations**Countries of recruitment**

Netherlands

Study participating centre

University Medical Center Utrecht

Utrecht

Netherlands

3508 GA

Sponsor information**Organisation**

University Medical Centre Utrecht (UMCU) (Netherlands)

ROR

<https://ror.org/04pp8hn57>

Funder(s)

Funder type

Research organisation

Funder Name

Dutch Kidney Foundation (Nierstichting Nederland) (Netherlands) (ref: pv-01)

Alternative Name(s)

Dutch Kidney Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Funder Name

Netherlands Heart Foundation (Nederlandse Hartstichting) (Netherlands) (ref: 2003B261)

Funder Name

Amgen (Netherlands)

Alternative Name(s)

Amgen Inc., Applied Molecular Genetics Inc.

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Pfizer (Netherlands)

Alternative Name(s)

Pfizer Inc., Pfizer Consumer Healthcare, Davis, Charles Pfizer & Company, Warner-Lambert, King Pharmaceuticals, Wyeth Pharmaceuticals, Seagen, Pfizer Inc

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Funder Name

Genzyme (Netherlands)

Alternative Name(s)

Genzyme Corporation

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2008		Yes	No
Results article	results	01/11/2010		Yes	No
Results article	substudy results	24/04/2012		Yes	No
Results article	results	01/09/2012		Yes	No
Results article	post-hoc analysis results	01/01/2014		Yes	No
	results				

Results article		01/02/2014	Yes	No
Results article	results	01/08/2015	Yes	No
Protocol article	protocol	01/01/2005	Yes	No
Protocol article	protocol	30/03/2006	Yes	No