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

Submission date	Recruitment status	[_] Prospectively registered
16/05/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/05/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/05/2016	Urological and Genital Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multicentre randomised active-controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 AII-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. Anaema 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 measure
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 measures
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

Overall study start date
21/04/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
800

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)

Sponsor details
PO Box 85500
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3508 GA

Sponsor type
Hospital/treatment centre

Website
http://www.umcutrecht.nl/zorg/

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

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/01/2005		Yes	No
Protocol article	protocol	30/03/2006		Yes	No
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 article	results	01/02/2014		Yes	No
Results article	results	01/08/2015		Yes	No