Frailty in uremia: A survey on the effects of CKD 3-5 on physical functioning and -activity, quality of life and nutritional state

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nephropathies
Study type	Observational non invasive

Summary

ID

NL-OMON54748

Source
ToetsingOnline

Brief title
Frailty in uremia.

Condition

- Nephropathies

Synonym
Chronic kidney disease / Kidney faillure

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Health-related quality of life, Nutritional status, Physical activity, Physical functioning

Outcome measures

Primary outcome

The primary objective of the study is to assess the longitudinal effects of differences and changes in renal function at CKD stage 3-5 on physical functioning.

Secondary outcome

The secondary objectives of the study are to assess the longitudinal effects of differences and changes in renal function at CKD stage 3-5 on physical activity, nutritional status, cardiovascular function, quality of life, symptom burden, illness perception, anxiety and depression.

Study description

Background summary

The number of patients with chronic kidney disease (CKD) and end-stage renal disease is increasing rapidly worldwide. It is expected that the number of patients with late-stage CKD (stage 4 and 5) will increase even further. These prospects lead to an increasing necessity of predialysis care, not only to delay a decline in renal function but also to prevent the loss of important physical functions and quality of life in relation to physical frailty, which were apparent in our previous studies in predialysis, as well as dialysis patients. Earlier detection of these changes may facilitate early intervention and prevention.

Study objective

The primary objective of the study is to assess the longitudinal effects of

differences and changes in renal function at CKD stage 3-5 on physical functioning. The secondary objectives of the study are to assess the longitudinal effects of differences and changes in renal function at CKD stage 3-5 on physical activity, nutritional status, cardiovascular function, quality of life, symptom burden, illness perception, anxiety and depression. The third objective is to assess the relation between different methods used to assess body composition with muscle strength and physical activity.

Study design

This is a prospective longitudinal cohort study with a follow-up of 4 years. All diagnostic techniques are non-invasive and provide minimal burden to the patient. As a comparison, age matched healthy controls will also be included.

Study burden and risks

In this study, only non-invasive techniques will be used which pose a minimal burden to the patient. Blood sampling will coincide as much as possible with regular blood takings for clinical purposes. The study will not have direct benefit for the participants. Bioimpedance measurements will not be taken in patients with ICD or pacemaker.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients:
• The population consists of patients attending the predialysis out-patient clinic, in which stage 3-5
CKD is diagnosed.
• Age> or equal to 18 years.
• Ability to provide written informed consent.,

Controls:
• Age> or equal to 18 years.
• Ability to provide written informed consent.
• If known with hypertension: well controlled bloodpressure (systolic <140mmHg and/or diastolic <90mmHg) with the use of hypertensive medication

Exclusion criteria

Patients:
• Inability to provide informed consent
• Active symptomatic coronary artery disease or cardiac failure NYHA class III or IV, whitin 3 months before inclusion
• Active malignancies, with a life expectancy of less then 1 year
• Active infections, whitin 3 months before inclusion
CKD after transplantation
• For bioimpedance measurements: presence of ICD or pacemaker. There are no restrictions for other measurements in these patients.

Controls:
• Inability to provide informed consent
• Hypertension (with or without the use of hypertensive medication) with a blood pressure higher than 160 mmHg systolic and/or diastolic larger than 100 mmHg during the screening.
• Diabetes Mellitus
• Self-reported cardiovascular disease / chronic kidney disease

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2022
Enrollment:	131
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	24-04-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-09-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	11-05-2022

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-10-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-06-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-05-2025
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL68518.068.18