CALciPROTEIN crystallisation as Target in Endstage CKD: the T50 assay

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational invasive

Summary

ID

NL-OMON56996

Source
ToetsingOnline

Brief title
CALPROTECT

Condition

- Renal disorders (excl nephropathies)
- Vascular disorders NEC

Synonym
Kidney failure, renal insufficiency

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Eurostars

Intervention

Keyword: Calcification propensity, Diagnostic, Dialysis, Vascular calcification

Outcome measures

Primary outcome

The main endpoints in this study is the change of T50 during a haemodialysis session, the effect of serum storage on the T50, and the verification of the T50 reference range.

Secondary outcome

The cardiovascular biomarker measurements will be the secundary study parameters.

Study description

Background summary

Patients with Chronic Kidneys Disease (CKD) are at higher risk to developing cardiovascular complications, specifically those in later stages. Approximately 50% of all deaths among CKD patients are caused by cardiovascular disease. Calcification of the cardiovascular structures is a hallmark of CKD, and related to this high risk. Currently, there is no tool to determine the cardiovascular risk in this population in blood. The T50 is a novel in vitro diagnostic bioassay which provides a functional read-out of the crystallization of calcium phosphate in human blood, which drives the calcification process. This T50 in turn correlates independently with the patient*s cardiovascular risk. Importantly, the T50 of an individual is modifiable and can be improved by for example adjusting medication, certain variables of dialysate composition, or changing to another type of dialysis treatment. In this proposed study the course of T50 during different dialyses types and other known biomarkers in CKD patients will be evaluated. Additionally, the optimal conditions of handling of the samples for clinical use will be determined.

Study objective

In this study, two co-primary objectives are stated. The first one is to analyse the change of T50 during haemodialysis treatments. The second primary

objective is to determine the effect of pre-analytical variables on the T50 measurements, specifically the storage of serum samples, and determine the reference values. A secondary objective is to determine any association between the T50 and other cardiovascular biomarkers, specifically markers for early vascular damage and inflammation.

Study design

In this cross-sectional study, CKD stage 5 (CKD5) patients will be included who are treated with daytime haemodialysis (n = 20) or nocturnal haemodialysis (n = 20) (CKD5D). Multiple blood samples will be collected during a haemodialysis session from which T50 and other laboratory parameters will be determined. Additional blood samples will be collected for the assessment of pre-analytical variables. Serum will be aliquoted and stored at varying conditions after which the T50 will be measured again. The same will be done for samples collected from healthy individuals (n = 30). For the reference values only blood collected from healthy individuals will be used. Finally, a selection of cardiovascular biomarkers will be measured in all participants.

Study burden and risks

The CKD5D population in this study will already be treated with dialysis as a part of their routine treatment. Drawing a volume of blood is the major burden when participating in this study, even though this will not require venepunctures in these patients. As for healthy participants, the blood collection process can result in some pain due to the venepuncture. However, the volume of blood is small and will therefore not result in a major burden.

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

Healthy: 18 years or older, no renal diseases, no cardiovascular disease, no diabetes mellitus, no hypertension, informed consent
Patient: 18 years or older, diagnosed with CKD stage 5, treated with haemodialysis, informed consent

Exclusion criteria

For both groups: hospitalization, active illness (e.g. fever)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	12-09-2024
Enrollment:	70
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	11-09-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL85381.018.24