The effects of FGF23 and Klotho on vascular calcification in end stage renal disease patients;

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

Summary

ID

NL-OMON47072

Source
ToetsingOnline

Brief title
FGF23 and vascular calcification

Condition

- Renal disorders (excl nephropathies)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
End stage renal disease, end stage renal failure.

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: FGF23, Klotho, Pulse wave velocity, Vascular calcification

Outcome measures

Primary outcome

Serum FGF23, Klotho and vitamin D concentrations and their correlation with

arterial stiffness as measured by pulse wave velocity.

Secondary outcome

Correlation between carotid-femoral pulse wave velocity (cfPWV) and

WeSTElan-derived PWV (wePWV).

Study description

Background summary

Vascular calcification and arterial stiffness, precipitated by abnormal calcium and phosphate metabolism in CKD, are related to the high cardiovascular mortality in chronic kidney disease (CKD) patients1-3. High Fibroblast Growth Factor (FGF)23 levels are associated with endothelial dysfunction, direct toxic effects to the cardiac myocytes leading to left ventricular hypertrophy and higher risk of cardiovascular events 4-7. The effects of elevated FGF23 levels on vascular calcification remains controversial 8, 9.

Study objective

The goal of this study is to evaluate if serum FGF23 levels are directly related to cardiovascular calcification, measured as arterial stiffness with pulse wave velocity. The primary objective is to evaluate if elevated serum FGF23 and decreased klotho and vitamin D (25 (OH)D) concentrations are related to increased arterial stiffness as measured by a carotid-femoral pulse wave velocity meter in patients with chronic kidney disease.
As a secondary objective, the study assesses correspondence between pulse wave velocity estimated from skin reflectivity (photoplethysmogram, PPG) and acceleration data simultaneously acquired at wrist, ankle and torso and pulse wave velocity obtained using a carotid-femoral pulse wave velocity meter.

Study design

Cross-sectional single center study.

Study burden and risks

Patients visit the out-patient clinic for routine check-up including their regular blood sample drawn, which we will use to measure FGF23, klotho and vitamin D concentrations. During this same appointment, patients undergo a single lead ECG measurement , a carotid-femoral pulse wave velocity measurement (cfPWV) and skin reflectivity (PPG) and acceleration measurements at wrist, ankle and torso.

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

Participating in the (pre)dialysis program
Informed consent.

Exclusion criteria

Age below 18 years.
Withdrawal of consent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2017
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	SpygmoCor CVS - pulse wave velocity meter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-09-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-04-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL54602.100.17