

Vitamin C status in patients with chronic kidney disease

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The goal of this study is to assess the prevalence of vitamin C deficiency in patients with end stage renal disease (Endogenous Creatinin Clearance (ECC) 30 ml/min) (NTx), peritoneal dialysis (PD), conventional (CHD) and nocturnal in-center...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vitamin related disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40228

Source

ToetsingOnline

Brief title

Vitamin C status in patients with chronic kidney disease

Condition

- Vitamin related disorders
- Renal disorders (excl nephropathies)

Synonym

vitamin C deficiency; chronic kidney disease

Research involving

Human

Sponsors and support

Primary sponsor: Dialyse Centrum Groningen

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

Intervention

Keyword: Hemodialysis, Kidney transplantation, Peritoneal dialysis, Predialysis, Vitamin C

Outcome measures

Primary outcome

1. Predialysis patients: plasma vitamin C level; 2. NTx patients: plasma vitamin C level; 3. PD patients: plasma vitamin C level, 4. CHD patients: plasma vitamin C levels before, during and after dialysis; 5. NCHD patients: plasma vitamin C levels before, during and after dialysis. In all groups vitamin C intake will be assessed using a 24-hour recall questionnaire.

Secondary outcome

CHD (3 dialysate measurements),

- vitamin C measurements from the dialysate: 15 minutes after start dialysis, after 2 hours dialysis, and 15 minutes before the end of the dialysis treatment.
- total Kt/V (dialysis efficiency).

NCHD (4 dialysate measurements),

- vitamin C measurements from the dialysate: 15 minutes after start dialysis, after 3 hours dialysis, after 6 hours dialysis, and 15 minutes before the end of the dialysis treatment.
- total Kt/V (dialysis efficiency).

Laboratory measurements: Hemoglobin, sodium, potassium, urea, creatinine, alkaline phosphatase, calcium, phosphate, albumin, ferritin, TSAT, CRP, PTH (standard monthly measurements)

Study description

Background summary

Patients with kidney failure have various physical complaints and laboratory abnormalities. Vitamin C deficiency may play a causal role and contribute to cramping, iron deficiency, and immunity disorders. Unfortunately, there is scarce information in the literature on vitamin C deficiency and vitamin C intake in patients with kidney failure. Also the exact prevalence of vitamin C deficiency and its related symptoms in patients with kidney failure have not yet been systematically examined. Finally, it is not known what the exact cause of vitamin C deficiency is. It is plausible that various mechanisms play a role and that the intensity of the dialysis treatment is an important factor.

Study objective

The goal of this study is to assess the prevalence of vitamin C deficiency in patients with end stage renal disease (Endogenous Creatinin Clearance (ECC) <20 ml/min) and in patients on various forms of renal replacement therapy: kidney transplantation (ECC >30 ml/min) (NTx), peritoneal dialysis (PD), conventional (CHD) and nocturnal in-center hemodialysis (NCHD).

Study design

Cross-sectional observational study in different patient groups.

Study burden and risks

This research has no disadvantages for the participants, except drawing of a limited volume of blood. Blood sampling in predialysis, NTx and PD patients will take place during regular visits to the outpatient clinic and no extra venipuncture is necessary; the total blood volume for these patients is 10 ml (incl. 5 ml for storage). Blood sampling in CHD and NCHD patients is performed during the regular dialysis session. The total blood volume in these patients is 20 ml (3 x 5 ml + 5 ml for storage). The food questionnaires are taken during regular visits and will cost no additional time. Participation in this study will take little to no extra time. The results of the study could contribute to the quality of treatment of the patients.

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

Predialysis patients with minimal 3 months ECC \leq 20 ml/min

Kidney transplantation patients: minimal 6 months after kidney transplantation with ECC \geq 30 ml/min

PD patients: minimal 3 months peritoneal dialysis treatment

CHD patients: 3 x per week 4 hours dialysis (\pm 12 hours dialysis per week), minimal 3 months hemodialysis treatment

NCHD patients: every other night 8 hours dialysis (\pm 28 hours dialysis per week), minimal 3 months in nocturnal hemodialysis treatment

Exclusion criteria

Malabsorption, gastro intestinal diseases, oncological diseases, and absence of informed consent.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 22-02-2016

Enrollment: 140

Type: Actual

Ethics review

Approved WMO

Date: 28-08-2014

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL47374.042.14