Vitamin C status in patients with chronic kidney failure

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Vitamin C deficiency may play a role in the symptoms of patients with chronic kidney failure and eventually renal replacement therapy

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational non invasive

Summary

ID

NL-OMON23437

Source
Nationaal Trial Register

Brief title
Vitamine C status in patients with chronic kidney failure

Condition

- Renal disorders (excl nephropathies)

Synonym
.Vitamin C, deficiency, kidney failure

Health condition

Healthy persons and patients with chronic kidney disease in different stages

Research involving
Human

Sponsors and support

Primary sponsor: UMCG
Dialyse Centrum Groningen

Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

Plasma Vitamin C concentration

Secondary outcome

Vitamine C intake

Dialyses clearance of vitamin C

Other laboratory variables

Study description

Background summary

Rationale: 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.

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 <20 ml/min) and in patients on various forms of renal replacement therapy: kidney transplantation (NTx), peritoneal dialysis (PD), conventional (CHD) and nocturnal center hemodialysis (NCHD).

Study design: Cross-sectional observational study in different patient groups.

Study population: Predialysis patients, NTx, PD, CHD, and NCHD patients of 18 years or older.

Main study parameters/endpoints: 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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.

Study objective

Vitamin C deficiency may play a role in the symptoms of patients with chronic kidney failure and eventually renal replacement therapy

Study design

1 year

Intervention

Bloodsamples

Contacts

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Eligibility criteria

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

Inclusion criteria

- minimal 18 years old patients - Predialysis patients: min. 3 months a creatinine clearance of < 20 ml/min

- Transplantation patients: min. 6 months after transplantation and a creatinine clearance > 30 ml/min

- Peritoneal dialysis patients: min. 3 months in treatment

- Conventionel hemodialysis patients: 3x 4 hour/week, min. 3 months in treatment

- Nocturnal in center hemodialysis patients: every other night, min. 3 months in treatment

Exclusion criteria

- malabsorption

- gastro-intestinal disorders

- oncologic disorders

- absence of informed consent

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2014
Enrollment:	160
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	28-04-2014
Application type:	First submission
Review commission:	nWMO adviescommissie UMC 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
NTR-new	NL4501
NTR-old	NTR4677
Other	METC : 2014/033

Study results

Summary results
no