Vitamine C status bij patiënten met chronische nierinsufficiëntie

Gepubliceerd: 30-06-2014 Laatst bijgewerkt: 03-03-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	Nieraandoeningen (excl. nefropathieën)
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23437

Bron
Nationaal Trial Register

Verkorte titel
Vitamine C status bij patiënten met chronische nierinsufficiëntie

Aandoening

- Nieraandoeningen (excl. nefropathieën)

Aandoening

Healthy persons and patients with chronic kidney disease in different stages

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: UMCG
Dialyse Centrum Groningen
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Plasma Vitamin C concentration

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

1 year

Onderzoeksproduct en/of interventie

Bloodsamples

Contactpersonen

Publiek

Postbus 30.001
A. Ozyilmaz
Hanzeplein 1
Groningen 9700 RB
The Netherlands
050-3615469

Wetenschappelijk

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The Netherlands
050-3615469

Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)

Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- malabsorption

- gastro-intestinal disorders

- oncologic disorders

- absence of informed consent

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend
Doel:	Diagnostiek

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-11-2014
Aantal proefpersonen:	160
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	28-04-2014
Soort:	Eerste indiening
Toetsingscommissie:	nWMO adviescommissie UMC Groningen

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4501
NTR-old	NTR4677

Register
Ander register

ID
METC : 2014/033

Resultaten

Samenvatting resultaten
no