Dietary Sodium Restriction in Renal Transplant Recipients.

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Reduction in dietary sodium intake decreases blood pressure, extracellular volume and renal damage in renal transplant recipients.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22929

Bron
NTR

Verkorte titel
SORRT

Aandoening

Kidney transplantation

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Blood pressure;
2. Number of antihypertensives used.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Hypertension is present in >70% of renal transplant recipients and a known risk factor for cardiovascular morbidity, cardiovascular mortality, and graft failure. Volume expansion caused by high sodium intake might play an important role in the development and maintenance of hypertension in renal transplant recipients. Although the effects of dietary sodium restriction have been investigated in healthy subjects and patients with chronic kidney disease, this has not yet been studied in RTR.

Objectives:

Primary Objective:

1. To investigate the effect of dietary sodium restriction on blood pressure in renal transplant recipients.

Secondary Objective(s):

1. To investigate the effect of dietary sodium restriction on extracellular volume as measured by volume parameters such as NT-proBNP;

2. To investigate the effect of dietary sodium restriction on renal damage as measured by urinary protein and albumin excretion and excretion of tubulointerstitial damage markers.

Study design:

The study is designed as a 12 week randomized crossover clinical trial with two parallel groups.

Study population:

The study population will consist of male and female renal transplant recipients who are one year after transplantation or beyond.

Intervention:

Patients will be symmetrically randomized to a liberal sodium diet aimed at 150 mmol (9 grams) daily or a low sodium diet aimed at 50 mmol (3 grams) daily.

Main study parameters/endpoints:

1. Blood pressure and use of antihypertensive medication;

2. Plasma NT-proBNP;

3. Urinary protein and albumin excretion, and urinary excretion of tubulointerstitial damage markers.

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

Patients are asked to visit the outpatient clinic 4 times. Prior to these visits patients have to collect 24-hour urine of the previous day and fill in dietary questionnaires the three days prior to their visits. The potential benefit of a low sodium diet may be a reduction of blood pressure, with subsequent reduction of cardiovascular risk and local renal damage. It may furthermore be accompanied by decreased tendency for plasma volume expansion with a reduction in the tendency for development of heart failure. Participation in the study is on a free-will base. Patients will not receive any financial support or priority for treatment of other diseases in the clinic during this study. All costs that subjects need for transportation in order to attend the clinic for the study purpose will be reimbursed completely.

Doel van het onderzoek

Reduction in dietary sodium intake decreases blood pressure, extracellular volume and renal damage in renal transplant recipients.

Onderzoeksopzet

4 timepoints.

Onderzoeksproduct en/of interventie

Low dietary sodium intake (~50 mmol/day = 3 grams salt/day) vs liberal dietary sodium intake (~150 mmol/dayg = 9 grams salt/day). This is a crossover design with an intervention period of 6 weeks each.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Written informed consent;

2. Male and female transplant recipients;

3. Transplantation performed in the University Medical Center Groningen or Academic Medical Center Amsterdam;

4. Patients that are one year after transplantation or beyond;

5. 18 years or older;

6. Stable renal function at study entry;

7. Use of RAAS-blockade: either an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin receptor blocker (ARB).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Blood pressure < 120/80 mmHg;

2. Blood pressure > 160/95 mmHg;

3. Complaints or signs of orthostatic hypotension;

4. Creatinine clearance < 30 ml/min/1.73m2;

5. Proteinuria > 1.5 g/24h;

6. Being on a cyclosporine withdrawal regimen;

7. Rejection of the allograft for which a switch in immunosuppressive medication is necessary;

8. Severe general diseases or mental disorders making the participation in the study impossible;

9. Pregnancy;

10. Drug abuse;

11. No sufficient knowledge of the Dutch language to participate in the study;

12. Participation in another intervention study during or within a month prior to this study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2012
Aantal proefpersonen:	42
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-04-2013
Soort:	Eerste indiening

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	NL3785
NTR-old	NTR3951
Ander register	METC / CCMO : 2011.131 / NL36854.042.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A