Effects of dietary sodium restriction on blood pressure in renal transplant recipients: an intervention study

Published: 17-08-2011
Last updated: 29-04-2024

Primary Objective: •To investigate the effect of dietary sodium restriction on blood pressure and use of antihypertensive medication in renal transplant recipients.Secondary Objective(s): •To investigate the effect of dietary sodium restriction on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39389

Source
ToetsingOnline

Brief title
SORRT

Condition

- Other condition
- Cardiac disorders, signs and symptoms NEC
- Renal disorders (excl nephropathies)

Synonym
high blood pressure, hypertension

Health condition

hypertensie

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dietary sodium intake, Hypertension, Renal transplantation

Outcome measures

Primary outcome

- Blood pressure -and use of antihypertensive medication

Secondary outcome

- Plasma NT-proBNP

- Relative changes between low and liberal sodium intake in stroke volume,

cardiac output and SVR and baroreflex sensitivity as measured by NexfinTM (in

the AMC) both supine and after 5 minutes standing

- Urinary protein and albumin excretion

- Urinary excretion of tubulo-interstitial damage markers (e.g. KIM-1, NAG,

NGAL, AAP, TGFB, CTFG)

Study description

Background summary

Hypertension is present in more than 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.

Study objective

Primary Objective:
•To investigate the effect of dietary sodium restriction on blood pressure and use of antihypertensive medication in renal transplant recipients.

Secondary Objective(s):
•To investigate the effect of dietary sodium restriction on extracellular volume as estimated from volume parameters such as NT-proBNP and systemic haemodynamics (non-invasive estimations of stroke volume, cardiac output and systemic vascular resistance)
•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 multicenter randomized crossover clinical trial with two parallel groups.

Intervention

Patients will be symmetrically randomized to a liberal sodium diet aimed at 150 mmol (9 grams) daily (control group) or a low sodium diet aimed at 50 mmol (3 grams) daily (intervention group) for 6 weeks. After 6 weeks groups will cross-over from intervention group to control group and vice versa and follow the other diet for 6 weeks.

Study burden and risks

Patients are asked to visit the outpatient clinic 4 times. Prior to the last 3 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.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Written informed consent
- Male and female renal transplant recipients
- Transplantation performed in the UMCG/AMC
- Patients that are one year after transplantation or beyond
- 18 years or older
- Stable renal function at study entry
- Use of RAAS-blockade: either an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin receptor blocker (ARB)

Exclusion criteria

- Blood pressure < 120/80 mmHg
- Blood pressure > 160/95 mmHg
- Complaints or signs of orthostatic hypotension
- Creatinine clearance < 30 ml/min/1.73m2
- Proteinuria > 1.5 g/24h
- Severe general diseases or mental disorders making the participation in the study impossible
- Pregnancy
- Being on a cyclosporine withdrawal regimen
- Rejection of the allograft for which a switch in immunosuppressive medication is necessary
- Drug abuse
- No sufficient knowledge of the Dutch language to participate in the study
- Participation in an other intervention study during or within a month prior to this study

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2012
Enrollment:	42
Type:	Actual

Ethics review

Approved WMO

Date:	17-08-2011
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	11-06-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-02-2014
Application type:	Amendment
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
Other	Nederlands Trial Register TC3951
CCMO	NL36854.042.11