Renal sensing of the acidifying effect of sulphur-containing amino acids: consequences for the relation between protein intake and blood pressure

Published: 16-12-2008
Last updated: 06-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON32527

Source
ToetsingOnline

Brief title
Effect of dietary protein, peptides and amino acids on blood pressure

Condition

- Other condition

Synonym
Hypertension, raised blood pressure

Health condition

Nierfunctieverlies en hypertensie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: TIFN

Intervention

Keyword: Blood pressure, Protein intake

Outcome measures

Primary outcome

Systolic and diastolic blood pressure

Secondary outcome

Nierfunctie zoals weergegeven door creatinineklaring

Study description

Background summary

The kidney as a nutrient sensing organ plays a key role in the relation between dietary protein intake and blood pressure. Different amino acids may have opposing effects, dependent on whether they are involved in gluconeogenesis and/or ureagenesis or whether they are acidifying. Amino acids involved in gluconeogenesis and/or ureagenesis may have a blood pressure lowering effect, whereas several pathways may contribute to a blood-pressure raising effect of acidifying amino acids. Subjects with subclinical renal injury, such as elderly subjects, subjects with low renal functional mass such as renal transplant recipients and subjects with obesity-related conditions, such as metabolic syndrome and type 2 diabetes, will be more susceptible to the blood pressure raising effects than others. Therefore, safety effects of (increased) intake of (specific) dietary protein in subjects with compromised renal function need to be elucidated.

Study objective

The primary objective of this study is to unravel mechanisms by which dietary protein (fractions) could influence systolic and diastolic blood pressure in humans.

Study design

The study is designed as an observational epidemiological study.
Cross-sectional and prospective analyses will be performed in a cohort with renal transplant recipients.

Renal transplant recipients form a very high risk population. Beyond one year after transplantation, when threats of acute rejection and opportunistic infections have largely disappeared, cardiovascular disease, high blood pressure, and gradual decline of renal function unrelated to immunological rejection are major problems. Rates of cardiovascular death and return to dialysis are very high. Susceptibility for an effect of high ingestion of sulphur-containing amino acids on blood pressure would be very high. This population should also be extremely susceptible to dietary intervention. Because of their high susceptibility, our hypothesis predicts amongst others that variation in dietary ingestion of sulphur-containing amino acids within subjects is associated with variation in blood pressure. This population is therefore extremely interesting for testing the effects of dietary intervention.
First we will collect data on dietary intake using the dietary questionnaire. Each patient visits our outpatient clinic at least once a year, and 24h urine collections and blood samples are gathered by routine, in combination with assessment of blood pressure and body weight. This will allow us to perform cross-sectional analyses initially and prospective analyses on development of hypertension and changes in blood pressure, in which variation in dietary sodium intake and other relevant parameters can be taken into account. From the fresh 24h urine samples to be collected amongst others urinary creatinine, bicarbonate, titratable acidity and ammonia will be determined in addition to urinary sodium, urea and sulphate.
Because under steady state conditions intake equals output, assessments of food substances and metabolites in 24h urine collections reflect dietary intake for many food components. Potential modification of these relations by sodium intake and body mass index can also be investigated.

Study burden and risks

There are no direct benefits for the patients to be included. 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.
Patients will be asked to fill in questionnaire concerning their dietary intake and lifestyles. During their visit, blood pressure, height and weight will be measured and fasting blood samples will be drawn.
Participation is accompanied with only minor risks. Venapunctures can occasionally cause a local haematoma and some participants may report some discomfort. All further performed measurements are non-invasive and risks are therefore minimal.
Since patients will be seen at a regular visit to the outpatient clinic, no extra costs for transportation to attend in the clinic for the study purpose

are needed.

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

Male and female renal transplant recipients
Patients that are (beyond) one year after transplantation
Transplantation performed in de UMCG
Written informed consent

Exclusion criteria

Dependence on renal dialysis
Severe general diseases or mental disorders making the participation in the study impossible
Drug abuse

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2008
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO

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	NL24007.042.08