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

Published: 09-01-2009
Last updated: 06-05-2024

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

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

Summary

ID

NL-OMON32729

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

nierfunctie(verlies) 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

Renal function as represented by creatinine clearance

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 type 1 diabetes and 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 patients with diabetes.

Patients with diabetes form a high risk population in which intervention may offer greater benefits than in low risk populations. Our hypothesis predicts that patients with diabetes are more susceptible to the blood pressure raising effects of renal sensing of the acidifying effect of ingestion of sulphur-containing amino acids than healthy subjects. Patients with diabetes frequently have mild renal function disturbances and a high prevalence of hypertension. A cohort of more than 1200 patients with diabetes is visiting at least once yearly our outpatient clinics. As already mentioned renal function may be an important mediator of susceptibility for the effect of high intake of sulphur-containing amino acids on blood pressure, while dietary sodium intake and urinary mineralocorticoid excretion volume may be other important determinants.

We will collect data on dietary intake using a dietary diary and a questionnaire. Questions concerning patient*s lifestyles (e.g. smoking behaviour, habitual physical activity) will be included as well. Patients with diabetes will have to be instructed how to collect 24h urine samples and containers will have to be sent to them. Follow-up of the patients will be automatic, as diabetic patients visit our outpatient clinics usually 3 times a year, and at least once a year.

Collection of fresh 24h urine samples will provide us with urine samples from which amongst others urinary bicarbonate, titratable acidity and ammonia can be determined in addition to urinary sodium, urea, sulphate, cortisol and alsosterone. Repeated assessment of blood pressure, body weight, and assessments in 24h urine collections will not only allow for initial cross-sectional analyses, but also for prospective analyses of development of hypertension and changes in blood pressure, in which variation in dietary sodium intake and other relevant parameters can be taken into account.

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. Samples of 24-hour urine have to be collected by the patients.

During their visit, blood pressure, height and weight will be measured. Fasting blood samples will be drawn during the venapuncture that is already performed for regular clinical patient care. No further invasive measurements will be executed and therefore risks of participation in this study are minimal, if present at all. 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 patients with type 1 or type 2 diabetes
Follow-up taking place in the outpatient clinics in the University Medical Center in Groningen,

the Isala Clinics in Zwolle and the Twenteborg Hospital in Almelo
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:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	850
Type:	Anticipated

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	NL24974.042.08