Influence of a Catecholamine-Rich Diet on Plasma and Urine Free and Total Metanephrine, Normetanephrine and 3-Methoxytyramine Concentrations.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Adrenal gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON32228

Source
ToetsingOnline

Brief title
The influence of a catecholamine-rich diet on metanephrines.

Condition

- Adrenal gland disorders

Synonym
Pheochromocytoma, tumor of the adrenal medulla

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: Catecholamines, Diet, Metanephrines, Pheochromocytoma

Outcome measures

Primary outcome

Free and total metanephrines and free catecholamines are measured in both

plasma and urine.

Secondary outcome

Genotypes of enzymes in the catecholamine metabolic pathway.

Study description

Background summary

The clinical chemical diagnosis of pheochromocytoma is based on the demonstration of an elevated catecholamine production rate. For this, quantitative analysis of plasma and urinary free catecholamines (i.e. epinephrine (E), norepinephrine (NE) and dopamine (DA)) and of their metabolites, mainly the respective 3-O-methylated metabolites (metanephrines, MNs) metanephrine (MN), normetanephrine (NMN) and 3-methoxytyramine (3-MT), are routinely performed in many laboratories
Several food products contain substantial quantities of biogenic amines. For example, DA and serotonin, and to a lesser extent NE, have been found in relatively high amounts in bananas, pineapples and walnuts. Consumption of such catecholamine-rich food products may increase plasma and urinary catecholamines and each of their metabolites, and thereby produce false-positive test results with respect to the diagnosis of pheochromocytoma.
Measurement of plasma free 3-O-methylated catecholamines (metanephrines) is the current method of choice for diagnosing pheochromocytoma, but it is unknown whether this procedure is affected by consumption of catecholamine-containing food products.

Study objective

The aim of the present study is to assess the necessity of dietary restrictions before sampling for the biochemical diagnosis of pheochromocytoma. Therefore,

the short-term influence of a catecholamine-rich diet on plasma free and total metanephrine concentrations is investigated. Urinary MNs and plasma and urinary free catecholamines are simultaneously measured in order to determine which test is least influenced by dietary compounds, specifically catecholamine-rich food.

Study design

Twenty healthy adults consume catecholamine-rich nuts and fruits (mainly containing dopamine) at six fixed times within a single day. Timed blood and urine samples are collected. Two days earlier the same protocol is carried out with catecholamine-low products instead of catecholamine-rich products. Blood is sampled in supine position after 30 min rest, by an intravenous sampling line that is received by the participant in the morning to avoid influence of sampling stress. Urine is collected over fixed time intervals until the morning after the experimental day.
Isotope-dilution mass spectrometry is used for the quantification of metanephrines and catecholamines.

Study burden and risks

During two days (9 hours per day) participants receive an intravenous line from which at six fixed times blood is samples. During 24 hours urine is collected divided over six fixed time intervals. The participants have to follow the diet scheme on those two days. There are no risks for participating in this study.

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

Healthy adults who gave written informed consent

Exclusion criteria

People that use certain medication that interrupt in the catecholamine-metabolism (like MAO-inhibitors, opiats and methyl-dopa). Also excluded from the study are non-healthy persons and pregnant women.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	20
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	NL20324.042.07