Investigation of the possible influence of using blood pressure lowering drugs on plasma free metanephrines concentrations.

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The objective of the study is to determine whether it is necessary to take the blood pressure lowering medication (β-blocker, ACE-inhibitors or diuretics) of a patient into account prior to blood sampling for pheochromocytoma diagnostics....

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

Summary

ID

NL-OMON38391

Source
ToetsingOnline

Brief title
Influence of blood pressure lowering drugs on plasma free metanephrines.

Condition

- Other condition
- Adrenal gland disorders

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: antihypertensiva, hypertension, interference, plasma metanephrines

Outcome measures

Primary outcome

Free metanephrines (i.e. metanefrine, normetanefrine en 3-methoxytyramine) are

measured in plasma.

Secondary outcome

Nvt

Study description

Background summary

Since the characteristic of pheochromocytoma is the increased catecholamine (eprinephrine, norepinephrine and dopamine)production in the tumor, its diagnosis is mainly based on clinical chemical results. In order to demonstrate the increased catecholmaine production, free catechooamines and/or their metabolites are measured in urine and/or plasma. The analysis of the free form of 3-O-metabolized catecholamines (metanephrine, normetanephrine and 3-methoxytyramine) in plasma is the most sensitive and specific method. Therefore the measurement of plasma free metanephrines is the golden standard for the diagnosis of pheochromocytoma. This method is, as far as known, not susceptible to analytical interferences. In contrast, physiological interference could be possible for example by the use of blood pressure lowering drugs, since such medication acts on teh catecholamine biochemistry. However, it is currently unknown whether the use of these drugs causes false-positive results when measuring plasma free metanephrines.

Study objective

The objective of the study is to determine whether it is necessary to take the blood pressure lowering medication (β-blocker, ACE-inhibitors or diuretics) of a patient into account prior to blood sampling for pheochromocytoma diagnostics. Therefore the influence of the use of this medication on plasma free metanephrine concentrations is established. Every patient is its own control.

Primary reserach question:
Does the use of beta-adrenoreceptor blocking drugs, angiotensine converting enzyme inhibitors or diuretics cause an increase of plasma free metanephrines which leads to false-positive pheochromocytoma diagnosis and is it therefore necessary to stop this medication prior to blood sampling?

Secundary reserach question:
Is there a difference between the use of a β-blocker, ACE-inhibitor or diuretics as blood pressure lowering drug?

Study design

Fifty adults are asked to join the study when through screening by the general practitioner or physician untreated hypertension, peripheral oedema, palpitations or migrain was discovered. Subsequently 10 ml extra blood is drawn during routine measurements for the determination of the metanephrines basal concentrations, and the β-blocker, ACE-inhibitor or diuretics are prescribed. After one-three months of treatment the patient is seen for follow-up. Blood pressure is measured again and again 10 ml extra blood is drawn for the analysis of plasma free metanephrines.
Blood is sampled in sitting position by venapunction, in addition to the routine blood sampling.
Metanephrines are quantitated by isotope dilution mass spectrometry.

Intervention

Blood pression lowering drugs in the normal treatment of hypertension.

Study burden and risks

During a regular visit to the general practitioner or physician, blood will be sampled twice: before treatment with a blood pressure lowering drug and after one-three months of treatment. Medical risks due to participation in the study is minimal.

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

Untreated hypertension, periferal oedema, palpitations or migrain.

Exclusion criteria

Treated hypertension.
Normal or low blood pressure. If there is no indication to start with -blocker, ACE-inhibitors or diuretics.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-02-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	19-03-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-09-2012
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
CCMO	NL24065.042.08