Salivary, plasma metanephrines and anxiety levels in pheochromocytomas

Published: 18-06-2015
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To determine the sensitivity and specificity of salivary metanephrines and in patients with PCC/sPGL.

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

Summary

ID

NL-OMON43844

Source
ToetsingOnline

Brief title
STRESS

Condition

- Adrenal gland disorders

Synonym
adrenal tumor, pheochromocytoma

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: Pheochromocytoma, Salivary metanephrines, Stress levels

Outcome measures

Primary outcome

The main study parameter is the diagnostic accuracy (sensitivity and specificity) of salivary levels of metanephrines assuming that the sensivity and specificity will be 95% (95% Confidence Interval (CI) 90-98%).

Secondary outcome

1. To evaluate the self-reported anxiety levels in patients with a PCC/sPGL, in comparison with healthy subjects and germline mutation carriers without elevated plasma metanephrines levels and to correlate the anxiety levels to the plasma metanephrines levels

2. To determine whether position (sitting vs. supine position) influences salivary metanephrines levels.

3. To establish a reference set for plasma and salivary metanephrines in supine position after 30 minutes of rest

4. To compare the ROC curves for the PCC/sPGL patients with the ROC curve of salivary and plasma metanephrines of asymptomatic germline mutation carriers.

5. To compare the concentration of metanephrines and catecholamines collected by venapunction versus a blood sample collected by an indwelling intravenous catheter

6. To establish a reference set of plasma catecholamines in supine position after 30 minutes of rest, and after 5 minutes of sitting

Study description

Background summary

Measurement of the O-methylated metabolites of plasma catecholamines (i.e. metanephrines) is the cornerstone in diagnosing pheochromocytoma (PCC) and sympathetic paragangliomas (sPGL)s. Levels of plasma metanephrines are, however, affected by body position during blood sampling. Therefore patients need to rest for 20 to 30 minutes in supine position before blood sampling. Measurement of levels of metanephrines in saliva could be an alternative, less cumbersome method, which also offers the advantage of collecting a diagnostic sample at home. Therefore, measurement of metanephrines in saliva is expected to be a novel, sensitive and more patient friendly method for the detection of PCC/sPGL. Furthermore catecholamines are involved in the physical sensations experienced in anxiety. Patients with PCC/sPGL have high levels of catecholamines, but anxiety levels never have been investigated.
Moreover, there are different methods to draw blood for the determination of plasma metanefrine levels, via indwelling catheter or via venapuncture, these differences never has been investigated.
Recently, the UMCG developed a new liquid chromatography in combination with isotope dilution mass spectrometry method for the simultaneous quantification of catecholamines (adrenaline, noradrenaline and dopamine) and metanephrines. This investigation is helpfull in the diagnosis of autonomic diseases, but reference levels are not established yet.

Study objective

To determine the sensitivity and specificity of salivary metanephrines and in patients with PCC/sPGL.

Study design

This study is a cross-sectional 2 center study performed at the University Medical Center Groningen (UMCG), Groningen, the Netherlands, at the National Institute of Health (NIH), Bethesda, USA and at the Radboud University Medical Center Nijmegen, the Netherlands

Study burden and risks

There is no or only one extra visit to the hospital and the study will take about 1 hour additional time. The medical risks and the burden for the patients and healthy subjects are considered to be minimal. If measurement of salivary metanephrines is just as accurate as plasma metanephrines is detecting a PCC/sPGL, this is time/costs effective for both patients and the hospital.

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

Age > 18 years
Group I: Patients with a PCC, or sPGL :
1. elevated plasma and/or urinary (nor)metanephrines
2. localization of a PCC or sPGL by anatomical (MRI/CT) and functional imaging (123I-metaiodobenzylguanidin (MIBG) scintigraphy or 18F-dihydrophenylalanine (DOPA) positron emission tomography (PET) or 18F-fluorodopamine PET.
Group II: Germline mutation carriers
1. plasma metanephrines in the normal reference range
Group III: Healthy subjects
1. normotensive.
2. no documented cardiovascular history (including: hypertension, diabetes, coronary artery disease, peripheral vascular disease),

Exclusion criteria

1. Age < 18 years
2. The need to use medication known to influence plasma metanephrines concentration: tricyclic antidepressants, phenoxybenzamine, MAO-inhibitors, sympathomimetics, cocaine, methyldopa
3. Patient who are operated on (after inclusion) and histology shows no PCC or sPGL
4. Patients, mutation carriers and healthy subjects who are not able to read and understand the Dutch language are not eligble for filling out the anxiety questionnair
5. Patient,mutation carriers and healthy subjects with severe psychiatric co-morbidity (i.e. acute suicidal ideations or behaviour, recently experienced psychosis, diagnosis of schizophrenia, bipolar disorder, drug abuse or substance dependence, serious cognitive or neurological problems) are not eligible for filling out the anxiety questionnaire.

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:	Recruitment stopped
Start date (anticipated):	30-06-2014
Enrollment:	315
Type:	Actual

Ethics review

Approved WMO

Date:	18-06-2015

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-12-2016
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

ID: 20291
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50957.042.14
Other	registratie verzoek ingediend NTR
OMON	NL-OMON20291