

Stress hormone dynamics in healthy individuals

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

Summary

ID

NL-OMON37912

Source

ToetsingOnline

Brief title

Stress hormone dynamics in healthy individuals

Condition

- Other condition

Synonym

functional somatic symptoms, medically unexplained symptoms

Health condition

Het betreft een beschrijving van de normale fysiologie. Uiteindelijk is deze kennis nuttig voor meerdere aandoeningen, aangezien stress hormonen worden beschouwd als generieke risicofactoren voor ongezondheid, waaronder medisch onverklaarde klachten.

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: catecholamine, cortisol, time series

Outcome measures

Primary outcome

levels of cortisol, catecholamines, and alfa-amylase in saliva, urine, hair, and nails

Secondary outcome

common somatic and psychiatric complaints

Study description

Background summary

Stress has been linked to medically unexplained symptoms and syndromes. It is often thought that these associations occur due to activations of the major stress-axes in the body: the hypothalamic pituitary adrenal-axis (HPA-axis) and the autonomic nervous system (ANS). Previous studies that typically used a single measurement of the activity of these systems, found small associations between stress axes activity and health. One important reason for these small associations is that stress axes fluctuations are only relevant in specific subgroups of patients, but it is currently impossible to identify these patients. An alternative design to study the role of the HPA-axis and the ANS in chronic fluctuating diseases is to use multiple repeated measurements within individual patients to study the associations between activity of the stress axes and symptom level. Such an analysis could be able to identify those patients in which symptoms occur following changes in HPA-axis and ANS activity. In order to develop a suitable assessment protocol for use in patients, we first need information on fluctuations in HPA-axis and ANS activity in healthy participants.

Study objective

The main objective is to study the intra-individual fluctuations in the physiological responsiveness of the HPA-axis and the ANS in healthy participants, and to test the influence of stressful events, sleep and activity on these fluctuations. The secondary objective is to study the associations between cortisol and catecholamine levels and common psychiatric and somatic symptoms within healthy individuals.

Study design

Observational study

Study burden and risks

Participants have to complete a diary for 9 weeks, assessing stressful events, sleep, activity, and symptom level. At the first day of this period, they also complete questionnaires on neuroticism, alexithymia and history of life events. On the first and the last day, they will be asked to provide a small sample of hair. In addition, they have to collect 24 hour urine, multiple saliva samples, and blood pressure and heart rate measures in this period. There are no risks associated with this procedure, and also no benefits.

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 Participants, aged 18-65 years.

Exclusion criteria

Use of medication, other than contraceptives or incidental paracetamol

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 09-07-2012

Enrollment: 10

Type: Actual

Ethics review

Approved WMO

Date: 12-04-2012

Application type: First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	20-06-2012
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	NL39630.042.12