Cortisol Levels in AcUte Stress moments

Published: 05-04-2018
Last updated: 11-04-2024

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

Summary

ID

NL-OMON46369

Source
ToetsingOnline

Brief title
CLAUS

Condition

- Other condition

Synonym
anxiety, Stress

Health condition

invloed van stress op hormoonspiegels in bloed (cortisol). Het betreft een onderzoek bij gezonde personen waarvan niet verwacht wordt dat ze een aandoening hebben.

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: researchgelden KCHL

Intervention

Keyword: Cortisol, First-responders, Stress, Trauma

Outcome measures

Primary outcome

- delta cortisol levels in blood/saliva (before, just after, en 10 hrs after

the exercise)

Secondary outcome

- correlation between biochemical parameters involved in glucose-metabolism and

cortisol levels

Study description

Background summary

Physiological stress is characterized by a steep increase of ACTH and cortisol in peripheral blood. An increase in cortisol levels leads to an increased gluconeogenesis and degradation of lipids. Also, an increased glucose level is seen in peripheral blood. It is known from earlier studies that extreme acute stress situations can lead to very high levels of cortisol. This in turn can lead to psychological blockade but also physiological complaints and even damage. It is reasonable that continuous training of certain possible stressfull situations can lead to a better handling of the stress feelings for that moment. At this moment a so-called "terroristic exercise" is planned for all caregivers involved in the Southwest part of Limburg (The Netherlands): ambulance-nurses, emergencyroom-nurses, police, fire department, but also a specialized military group (rapid response team) will take part in this exercise moment. Because the training level how to cope with certain stressfull situations differ between these group of caregivers, it is hypothesized that there will be a difference in cortisol levels before and after the exercise.

Study objective

The major objective of this study is to investigate the level and response in cortisol before and after a stressfull situations in different groups of care-givers. It is hypothesized that the best trained group will show the lowest increase in cortisol during and after stressfull situations. For our

case, this will be the military rapid-response team.
Next to this, questionnares will be used to investigate possible responses in cortisol levels and correlate them with possible coincidences.
Finally, this exercise will be used to validate our new cortisol-assay in saliva to the golden standard 'cortisol levels in plasma'. The new assay in saliva have certain benefits to the blood test (it is faster, high sensitivity and less invasive).

Study design

It will be an observational study which will be performed during the "disaster exercise" of the LVIZ (Limburgse Vereniging voor Intensieve Zorg; 19 april 2018). Before, just after, and 10 hrs after the exercise blood- and saliva samples will be collected in the different groups of care-givers (ambulance-nurses, emergencyroom-nurses, police, fire department, but also a specialized military group (rapid response team)).

Intervention

n/a

Study burden and risks

- correlation between cortisol in saliva and in peripheral blood

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 persons

Exclusion criteria

- no recent nightshift
- no diabetes

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):	19-04-2018
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	05-04-2018
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL65382.096.18