Military Genotyping Study: Individualizing fatigue and sleep deprivation tolerance in shift and night work

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There are large interindividual differences in tolerance for night work. The main factors determining this tolerance are largely unknown, and better identifying them - which is the aim of this study - may target preventive and mitigating strategies...

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

Summary

ID

NL-OMON51468

Source
ToetsingOnline

Brief title
Genotyping sleep and fatigue tolerance

Condition

- Other condition

Synonym
circadian clock, circadian rhythm

Health condition

Circadiane ritme

Research involving

Human

Sponsors and support

Primary sponsor: Koninklijke Landmacht
Source(s) of monetary or material Support: Ministerie van Defensie

Intervention

Keyword: chronotype, Circadian flexibility, genotype, Single Nucleotide Polymorphism

Outcome measures

Primary outcome

Compound set of Questionnaires:

- Chronotype Questionnaire

- Visuo-verbal Judgment Task

- Single-item Chronotype Scale: energy level throughout the day

- Munich Chronotype Questionnaire: chronotyping according tot the LIVEMAN-model

(Lethargic, Intermediate/Inconclusive, Vigilant, Evening, Morning, Afternoon,

Napping types)

- Pittsburg Sleep Quality Index (PSQI): sleepquality and sleep quantity

- Brief-Caffeine Expectancy Questionnaire: effects of cafeïne-containing

products

2. Genotyping 5 SNP*s (Adenosine A2A receptor (ADORA2A), Adenosine deaminase

(ADA), Catechol-O-methyltransferase (COMT), Tumor necrosis factor alpha (TNF-α)

en Period2 (PER3)) using the Whatman* FTA* Buccal collection selfkit

Secondary outcome

N/A

Study description

Background summary

A substantial part of the Dutch Defense labor force is regularly exposed to shift work and night work. Night work compromises the individual Circadian rhythm and may lead to fatigue and sleep problems, or eventually chronic illness.

Study objective

There are large interindividual differences in tolerance for night work. The main factors determining this tolerance are largely unknown, and better identifying them - which is the aim of this study - may target preventive and mitigating strategies for the least tolerable individuals.

Study design

Participants fill out a compound set of questionnaires regarding sleep behavior and sleep quality, chronotype and cafeïne intake. Saliva samples are taken from each participant to analyse their genotype profile on 5 SNPs (see Outcomes). Associations between questionnaire scores and genotyping are studied. We strive to include 100 participants into our study.

Study burden and risks

Time investment approx. 45 minutes. No known health risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Employee of the Netherlands Armed Forces

Exclusion criteria

Allergic reaction to wearing nitril hand gloves

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-10-2022
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO Date:	02-05-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	18-10-2022
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL80876.028.22