FTOP - nationwide observational study

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Fatigue affects central nervous system function and, in the setting of the medical profession, could influence specialist performance, patient care and safety. In contrast to other industries, for example the aviation industry, there are no...

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20811

Bron
NTR

Verkorte titel
FTOP (= Fit-to-Perform)

Aandoening

A set of active round-the-clock medical specialists as well as active medical registrars, both male and female, will be assessed for their performance on the FTOP test.

Ondersteuning

Primaire sponsor: Centre for Human Drug Research;
Nederlandse Vereniging voor Heelkunde;
Nederlandse Internisten Vereniging;
Nederlandse Vereniging voor Obstetrie & Gynaecologie;
Nederlandse Vereniging voor Kindergeneeskunde;
Nederlandse Vereniging voor Anesthesiologie.
Overige ondersteuning: Stichting Kwaliteitsgelden Medische Specialisten (SKMS)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary Objective
1. Determine the physiological and subjective fitness of selected around the-clock medical specialists in three different states of fatigue.

Toelichting onderzoek

Achtergrond van het onderzoek

This is a nationwide observational multicenter study to investigate the physical and mental state of around-the-clock medical specialists using the FTOP-test. Subjects will function as their own control. The FTOP-test will be performed on the Mini-NeuroCart, a modified version of a test system for assessment of CNS function. Performance of subjects will be assessed at multiple points in time including: non-call, pre-call, and post-call assessment. Testing will occur on site, thereby minimizing the effect on normal daily clinical activities.

Doel van het onderzoek

Fatigue affects central nervous system function and, in the setting of the medical profession, could influence specialist performance, patient care and safety. In contrast to other industries, for example the aviation industry, there are no "Fit to Perform" standards in medicine. With the wide implementation of quality of care monitoring systems, resident working hours limitations, expanding patient safety measures and increasing patient and governmental awareness about these aspects, it is imperative to develop an easy-to-use "Fit to Perform" test.
A nationwide multicenter study will be conducted to provide representative data on fatigue of around-the-clock medical specialists. Fitness-to-perform of medical specialists will be measured in three different states of fatigue: pre-call, post-call and rested. When compared to the previously created relevant frames of reference (social, personal, and professional), one can assess whether the level of fatigue is acceptable or not. This test can be implemented in clinical practice to serve as an easy-to-use tool to assess fitness to perform of around the-clock medical specialists, and provide a basis for working-hour reforms. Ultimately, outcomes of this test can be coupled to patient outcomes to provide data on the relation between doctor's fatigue and patient safety.

Onderzoeksopzet

1. Subjective outcome parameters:

a. Alertness

b. Mood

c. Personal stress level

d. Self-assessment of ability to perform (FTOP questionnaire)

2. Objective parameters:

a. Vigilance/Alertness (Adaptive tracking)

b. Visuo-motor coordination (Adaptive tracking)

c. General CNS-activity (Visual analogue scores reflecting drowsiness and fatigue)

Onderzoeksproduct en/of interventie

Effects of night-duty on performance

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Eligible subjects must meet all of the following inclusion criteria:

1. Subjects are around-the-clock medical specialists or medical registrars, employed at the participating hospitals within one of the following medical specialties:

a. Surgery;

b. Gynaecology;

c. Anaesthesiology;

d. Internal Medicine;

e. Paediatrics.

2. Informed consent has been provided.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Eligible subjects must meet none of the following exclusion criteria:

1. A condition that in the opinion of the investigator would complicate or compromise the study, or the well-being of the subject (e.g. decreased vision or limited range of motion in the forearm or wrist)

2. Any known factor or condition that might interfere with study compliance, study conduct or interpretation of the results.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-07-2015
Aantal proefpersonen:	1000
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	17-07-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5169

Register	ID
NTR-old	NTR5309
Ander register	Centre for Human Drug Research/Ethics Committee Leiden University Medical Center : CHDR1416/P14.318

Resultaten