No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

Source

NTR

Brief title

FTOP (= Fit-to-Perform)

Health condition

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.

Sponsors and support

Primary 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.
Source(s) of monetary or material Support :	Stichting Kwaliteitsgelden Medische Specialisten (SKMS)

Intervention

Outcome measures

Primary outcome

Primary Objective

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

Secondary outcome

Secondary Objectives

1. Compare the level of post-call fatigue to the relevant frames of reference;

2. Compare "Fitness to Perform" between different areas of medical specialization in the Netherlands;

3. Compare "Fitness to Perform" between different medical centres;

4. Increase knowledge about factors influencing "Fitness to Perform";

5. Compare subjective and objective levels of fitness and increase awareness regarding the possible dissociation between these levels.

Study description

Background summary

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.

Study objective

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.

Study design

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)

Intervention

Effects of night-duty on performance

Contacts

Public
Zernikedreef 8

C.R.H. (Coen) Huizinga
Leiden 2333 CL
The Netherlands
+31715246423
Scientific
Zernikedreef 8

C.R.H. (Coen) Huizinga
Leiden 2333 CL
The Netherlands
+31715246423

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type :	Observational non invasive
Intervention model :	Crossover
Allocation :	Non controlled trial
Masking :	Open (masking not used)
Control :	N/A , unknown

Recruitment

NL

Recruitment status :	Other
Start date (anticipated) :	01-07-2015
Enrollment :	1000
Type :	Unknown

Ethics review

Positive opinion

Date :	17-07-2015
Application type :	First submission

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
NTR-new	NL5169
NTR-old	NTR5309
Other	Centre for Human Drug Research/Ethics Committee Leiden University Medical Center : CHDR1416/P14.318

Study results