A single-centre, placebo-controlled, crossover study in healthy medical registrars to enable validation of the mini-neurocart with the laparoscopy box trainer

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38449

Source
ToetsingOnline

Brief title
FTOP - validation MiniNC

Condition

- Other condition

Synonym
Fit to perform test

Health condition

Validatiestudie fitheidstest (psychomotor/CNS) voor medisch specialisten

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: Ministerie van OC&W,Centre for Human Drug Research,Medisch Centrum Haaglanden,Nederlandse Vereniging voor Heelkunde

Intervention

Keyword: Clinical competence, CNS test battery, Fitness-to-perform, Laparoscopic box trainer

Outcome measures

Primary outcome

1. Subjective outcome parameters: VAS Bond and Lader

a. Alertness

b. Mood

c. Personal stress level

d. Self assessment of ability to perform

2. Objective parameters:

a. Vigilance/Alertness (Adaptive tracking)

b. Visuomotor coordination (Adaptive tracking)

c. Stop signal response inhibition (Stop Signal Test)

d. General CNS-activity (Visual analogue scores)

e. Laparoscopic motion and force tracking (Force Motion Surgical Trainer)

Secondary outcome

n/a

Study description

Background summary

It is widely accepted that fatigue and sleep deprivation negatively affect performance, varying from mood and cognitive function to motor performance. This is a problem for surgical specialists as they commonly work long shifts, perform under high pressure of making the right medical decisions, and are dependent upon motor skills during surgical procedures.

As a consequence for the patient, doctor*s fatigue could lead to an increased risk of surgical complications and negligence in care that could seriously endanger its safety. As a consequence to the doctor, this leads to high rates of stress and depression, somatic complaints, pregnancy-related problems, and even an increased risk of vehicle accidents.

Not surprisingly, the public and professional awareness of the issue of fatigue among doctors is increasing. However, what is to be considered *tired* and oppositely *fit* in the context of the medical specialist remains to be defined. Furthermore a relevant frame of reference of what can be considered acceptable or not is lacking.

To overcome these shortcomings, this study is designed to comprehensively explore the different aspects of fatigue of both surgical specialists and their residents, to relate these aspects to the validated effects of drugs on which legal limits have been set, and to define surgical fitness-to-perform.

The FTOP test is designed to target several CNS parameters of fitness that are all professionally relevant, enabling formation of an objective scale to assess the level of performance. Validation of these CNS scores with a laparoscopic trainer is necessary in order to create a professional frame of reference. The use of the ForMoST (Force Motion Surgical Trainer) box trainer, provides a means to objectively classify the performance of surgeons according to their laparoscopic skill.

Results from this study will provide the surgical specialist with a practical, validated tool, to help deciding whether to operate or not. Ultimately, a Fit to Perform test could limit performing under great tiredness, could increase the quality of life of surgical specialists, and could improve patient safety.

Study objective

This study has the primary aim to correlate subjective fitness of medical specialists to objective scales and relate the scores to validated levels of performance, which would be considered acceptable to perform surgical

procedures.

Objectives of this study using the Mini-NC and ForMoST box trainer in healthy specialist registrars are as follows:

Primary Objective:
Validation of the Fit tot Perform test using a laparoscopic box trainer.

Secondary Objective:
To compare the anticipated decreased scores in the Fit to perform test to the anticipated decrease in laparoscopy performance under the influence of ethanol.

Study design

This is a single-centre, placebo-controlled, crossover study with ethanol clamping in healthy medical registrars while performing tests on the FTOP-test and ForMoST box trainer. Subjects will function as their own control. The tests will be conducted during one testing day. Subjects will perform the tests in randomised order under administration of placebo and different levels of ethanol. By comparing the changes in scores of both the Mini-NC and the Laparoscopy-simulator, a correlation between the tests may be established and a cut-off value based on legal alcohol limits as well as pre-set professional laparoscopy requirements can be set. Taken together, these findings enable the validation of the Mini-NC with the laparoscopy box trainer.
The total duration of the study for each subject will be up to 21 days divided as follows:
* Screening: Up to 21 days before dosing;
* Treatment and study assessments: Day 1;
* In Clinic period: one day;
Subjects will be admitted to the Clinical Research Unit (CRU) and will be discharged approximately 12 hours after study drug administration.

Intervention

Ethanol intravenous administration:

Prior to a study occasion, the study statistician will prepare individual computer spreadsheets, according to a randomized schedule. For alcohol occasions, this spreadsheet contains a blank *measurement column*, in which the measured BrEC-values (breath ethanol concentration) are entered by the infusion assistant. Based on these results, the spreadsheet calculates the new infusion rate.
1. The clamping procedure will be initiated to achieve a stable pseudo-steady state level of 0.3 g·L-1; a spread sheet-based paradigm using BrEC guided adjustments of infusion rates will be used to maintain stable levels.
2. Clamping procedure will be modified to achieve a stable pseudo-steady state

level of 0.6 g·L-1; a spread sheet-based paradigm using BrEC guided adjustments of infusion rates will be used to maintain stable levels.

Placebo intravenous administration:

For placebo occasions, the spreadsheet contains a separate column with *sham* BrEC-values, determined from kinetic simulations. At each protocol time, the infusion assistant will enter the corresponding *sham* value into the measurement column. This value will be used by the spreadsheet to calculate a new *sham* infusion rate, which can be applied accordingly. In this manner, operations during the alcohol clamping and sham procedures are exactly similar for the subject. At measuring times identical to the clamping procedure, subjects will perform tests on the ForMoST laparoscopy box trainer and FTOP-test.

Study burden and risks

Depending on randomization, subjects in this study can be subjected to placebo or the depressant ethanol.

The nature of the study requires subjects to be present at the CHDR for a total of one day; this may interfere with the normal work schedule of these registrars. Participating subjects will be financially compensated.

Contacts

Public
Centre for Human Drug Research

Zernikedreef 8
Leiden 2333CL
NL
Scientific
Centre for Human Drug Research

Zernikedreef 8
Leiden 2333CL
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.Subjects are healthy specialist registrars in one of the following specialist fields of medicine;
a. Surgery;
b. Urology;
c. Gynaecology.
2. Subjects have completed one/both of the following courses: advanced Suturing Course (ASC) or OCEH;
3. Written informed consent;
4. Willing to comply with the study restrictions.

Exclusion criteria

1. Comorbidity or used pharmacological agents affected by alcohol;
2. Subject did not abstain from alcohol usage during the period from 48 hours prior to testing until discharge from the CRU;
3. Subject is is not able to refrain from use of (methyl) xanthines (e.g. coffee, tea, cola, chocolate) from 48 hours prior to dosing until discharge from the CRU;
4. Subject has used other stimulant or depressant medicines or substances during the 24 hours prior to testing;
5. Subject is unable to refrain from the use of concomitant medication which, in the opinion of the investigator, interferes with their ability to participate in the study, from 7 days prior to dosing until discharge from the CRU;
6. Subject does not have veins suitable for cannula placement;
7. Any other condition that in the opinion of the investigator would complicate or compromise the study, or the well being of the subject.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2013
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	20-11-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL46116.058.13