Effects of Modafinil and Caffeine on vigilance in low, medium and high caffeine consumers during the circadian trough in healthy RNLAF aircrew

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22963

Source
Nationaal Trial Register

Brief title
MOCAFFE

Health condition

vigilance (fatigue)- waakzaamheid (vermoeidheid)

Sponsors and support

Primary sponsor: n.a.
Source(s) of monetary or material Support: The Dutch Ministry of Defence

Intervention

Outcome measures

Primary outcome

Vigilance &Tracking Test (VigTrack):

- root mean square of tracking error

- percentage omissions

- reaction time

Psychomotor Vigilance Task (PVT):

- reaction time (RT)

- lapses

- misses

Stanford Sleepiness scale (SSS)

Epworth Sleepiness scale (ESS)

Secondary outcome

n.a.

Study description

Background summary

To investigate the effect of modafinil (200 mg) and caffeine (300 mg) on vigilance in low, medium and high caffeine consumers during the circadian trough in order to determine the best pharmacological agent to target fatigue. This is a randomized, double-blind, placebo controlled, three treatment, three nights, crossover-intervention study. Groups will be selected based on their daily caffeine intake. All groups will spend three non-consecutive nights at the research centre in which they will be given 200 mg modafinil, 300 mg of caffeine and a placebo.

Study objective

Primary Objective: Investigate the effect of modafinil (200 mg) and caffeine (300 mg) on vigilance in low, medium and high caffeine consumers during the circadian trough in order to determine:

- To what extend vigilance during the circadian trough is elevated by caffeine and modafinil

- If the extent to which modafinil, compared to caffeine, promotes alertness is dependent on the daily amount of caffeine intake.

Study design

All groups will spend three non-consecutive nights at the research centre in which they will be given 200 mg modafinil, 300 mg of caffeine and a placebo. On the test day they will be welcomed and the procedures for the day will be explained. Also, they will need to fill out the Epworth and Stanford Sleepiness Scales. After procedures have been explained, first bloodsamples of subjects will be taken to determine caffeine levels. Also the subjects' vital parameters will be measured, including blood pressure, temperature (aural or oral) and pulse.
A pregnancy test will be performed on every test day. The Psychomotor Vigilance Task (PVT) and Vigilance & Tracking Test (VigTrack) will be practiced and explained to them. During the three test days subjects are allowed to do whatever they want for the rest of the day, although they cannot leave the test center without being chaperoned. Also, subjects are not allowed to fall asleep. Based on the amount of caffeine intake that they habitually use, they should take their normal amount of caffeine based products, no caffeine consumption is allowed after 17:00. At 18:00 first baseline characteristics will be measured, including blood pressure, pulse, temperature, bloodsamples, Stanford Sleepiness scale and a series of VigTrack and PVT tests. At 0:00 another baseline measure with a set of VigTrack, PVT tests and bloodsamples will be done, and directly after, subjects will get their test medication (modafinil or caffeine or placebo). From then on, at 2:00, 3:00, 4:00, 6:00 and 8:00 subjects will do another set of VigTrack and PVT and blood will be sampled the same way as mentioned before

Intervention

200 mg Modafinil: Wakefulness promoting agent (psychostimulant)

300 mg Caffeine: Alertness aid.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

I. The potential participant has given informed and written consent and is able to comply with all study assessments scheduled in the protocol.

II. All personnel need to be aircrew members of the Royal Netherlands Air Force, irrespective of their position.

III. All subjects need to be between 18 and 60 years of age.

IV. All subjects need to be in good health, and may not have any chronic diseases.

V. All female subjects need to take supplementary contraceptives, if they are using the birth control pill as the contraceptive of choice.

VI. Subjects must be able to communicate, participate, and comply with the requirements of the entire study, including completion of all the visits along with the domiciled periods and sleep questionnaires.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

Exclusion criteria are mostly based on possible side effects or interactions of one or both of the medicines.

i. Pregnant or nursing women, as modafinil is possibly teratogenic. There has not been enough research to prove modafinil is safe for use during pregnancy. A pregnancy test will be performed on every test day.

ii. People with known heart, kidney or liver disease or neurological complaints.

iii. People who use medication that is being metabolized through CYP3A4/5, CYP2C19 of

CYP2C9, since this might alter the plasma levels of the used medication and modafinil.

iv. A history of psychiatric illness; this includes sleeping disorders

v. One week prior to starting every trial day, all subjects need to be (and remain) in a time zone that is a maximum of 4 time zones away from the CET time zone in which the research center lies. (GMT+1, daylight savings GMT+2). This to exclude jet lags that might confound the test results.

vi. Known allergies for caffeine, modafinil or any of its ingredients or metabolites.

Women using hormone based birth control (e.g. oral contraceptives, intra-uterine device) will be very well informed prior to taking part due to the interference between hormones and modafinil. There will be no interference with the working mechanism of modafinil or its efficacy, but there is a known decreased effect of the contraceptive when used simultaneously with modafinil.
Women using hormone-based contraceptives can therefore participate if they are willing to use other non-hormone based contraceptives as well. It is therefore not a direct exclusion criterion, but women will be informed concerning the lower efficacy of hormonal contraceptives.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-04-2018
Enrollment:	36
Type:	Unknown

Ethics review

Not applicable
Application type: Not applicable

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	NL6744
NTR-old	NTR6922
Other	METC Brabant // NL. Nummer // EudraCT nummer : P1749 // NL62145.028.17 // 2017-002288-16

Study results

Summary results
n.a.