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

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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...

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22963

Bron
Nationaal Trial Register

Verkorte titel
MOCAFFE

Aandoening

vigilance (fatigue)- waakzaamheid (vermoeidheid)

Ondersteuning

Primaire sponsor: n.a.
Overige ondersteuning: The Dutch Ministry of Defence

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

200 mg Modafinil: Wakefulness promoting agent (psychostimulant)

300 mg Caffeine: Alertness aid.

Contactpersonen

Publiek

Y.Q. Wingelaar-Jagt
Kampweg 3

Soesterberg 3769 DE
The Netherlands
+31 (0)346 33 4300

Wetenschappelijk

Y.Q. Wingelaar-Jagt
Kampweg 3

Soesterberg 3769 DE
The Netherlands
+31 (0)346 33 4300

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-04-2018
Aantal proefpersonen:	36
Type:	Onbekend

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

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

Resultaten

Samenvatting resultaten
n.a.