The effect of caffeine on attention

Published: 29-08-2014
Last updated: 22-04-2024

The primary objective is to determine whether 60 mg caffeine improves sustained attention. The primary outcome measures will be the Rapid Visual Information Processing task (RVIP) (selected based on the scientific evaluation that deemed this type of...

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

Summary

ID

NL-OMON41150

Source
ToetsingOnline

Brief title
Caffeine*s effect on attention

Condition

- Other condition

Synonym
NA

Health condition

NA

Research involving
Human

Sponsors and support

Primary sponsor: Nestec Ltd
Source(s) of monetary or material Support: Nestec Ltd

Intervention

Keyword: attention, Caffeine, healthy volunteers, saliva concentration

Outcome measures

Primary outcome

Primary objective and outcome:

The primary objective is to confirm whether 60mg caffeine improves sustained attention. The primary outcome tests will be the Rapid Visual Information Processing task (RVIP) and the Mackworth Clock test. RVIP was selected based on the scientific evaluation that deemed this type of sustained attention test as most sensitive to caffeine*s effects at low doses in healthy adults. The Mackworth Clock was selected to assess sustained attention performance over a long period of time.

Secondary outcome

Secondary objectives and outcomes:

1. Sustained attention: RVIP and Mackworth Clocktest: number of hits

2. Evaluate the effects of 60 mg caffeine on mood.

3. Effect of caffeine on other CNS domains as described above.

4. Saliva concentrations of caffeine for compliance and correlation relationship with attention

Study description

Background summary

In April 2011, the European Food Safety Authority (EFSA) gave a positive opinion for two health claims relating to mental performance (increased alertness and improved concentration) for beverages containing at least 75 mg caffeine per serving for the general adult population. Nestec Ltd would like to further explore the effects of 60 mg caffeine on mental performance.
Based on a scientific evaluation, among alertness, sustained attention (also known as vigilance) and selective attention, sustained attention was found to be the most sensitive to the stimulating effects of low dose caffeine (less than 75 mg caffeine) in adults. Thus, this clinical trial will be conducted to demonstrate positive effects of 60 mg caffeine on sustained attention versus placebo.

Study objective

The primary objective is to determine whether 60 mg caffeine improves sustained attention. The primary outcome measures will be the Rapid Visual Information Processing task (RVIP) (selected based on the scientific evaluation that deemed this type of sustained attention test as most sensitive to caffeine*s effects at low doses in healthy adults) and the Mackworth Clock test (selected to assess sustained attention performance over a long period of time).

The secondary objectives are to evaluate:
1. The accuracy for RVIP task and Mackworth Clock test
1.2. Evaluate the effects of 60mg caffeine on mood.
1.3. The effect of caffeine on other CNS domains as described above.
1.4. Saliva concentrations of caffeine for compliance and correlation relationship with attention

Study design

Single centre single dose cross-over, placebo-controlled, double blind randomised-control trial with two treatment conditions: caffeine (60mg) and placebo.

Intervention

1. Caffeine capsule (60mg)
2. Placebo (mannitol)

Study burden and risks

Caffeine has few unwanted side effects and is safe. As only a single relatively low dose of caffeine will be administered per occasion, we do not expect that these side effects occur, with exception of changes in heart rate and blood pressure and short-term increased diuresis.

Contacts

Public
Nestec Ltd

Avenue Nestlé 55 N/A
Vevey CH-1800
CH
Scientific
Nestec Ltd

Avenue Nestlé 55 N/A
Vevey CH-1800
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age between 40-50 years (inclusive)
- Healthy male and female adults (healthy status is defined by absence of evidence of any active or chronic disease following a detailed medical history, a complete physical examination including vital signs).
- Minimum weight of 60 kg and maximum of 85 kg.
- Average consumption of less than 150 mg of caffeine per day within the last week.
- Able to abstain from caffeine-containing foods and beverages and alcohol 24 hours prior to each testing session.
- Ability to communicate well with the investigator in the local language.
- Able to participate, willing to give written informed consent and to comply with the study restrictions.

Exclusion criteria

- History or symptoms of any significant disease or condition including (but not limited to), visual, auditory, neurological, psychiatric, endocrine, cardiovascular, respiratory, gastrointestinal, hepatic, or renal disorder that could interfere with, or for which the treatment of might interfere with, the conduct of the study, or that would, in the opinion of the investigator, pose an unacceptable risk to the subject in this study.
- Systolic blood pressure (SBP) greater than 140 or less than 90 mm Hg, and diastolic blood pressure (DBP) greater than 90 or less than 50 mm Hg.
- History or clinical evidence of alcoholism or drug abuse within the 3-year period prior to screening.
- History of smoking (tobacco-based products) within 12 months prior to screening.
- Positive test for drugs of abuse.
- Pregnancy (anamnesis).,
- No prescription medications, over the counter (OTC) medications, vitamin, herbal and dietary supplements will be permitted within 7 days prior to study drug administrations, or less than 5 half-lives (whichever is longer, and during the course of the study). This will be extended to substrates, inhibitors and inducers of the CYP1A2 (including broccoli, brussel sprouts, char grilled meat) and CYP3A4 (including starfruit and St John's wort). Exceptions are paracetamol (up to 4 g/day) and ibuprofen (up to 1 g/day), medications for controlling blood pressure and cholesterol, and contraceptives. Other exceptions will only be made if the rationale is discussed and clearly documented between the investigator and the sponsor.
- Subjects of the morning or eveningness type (extreme) based on a Horne and Östberg questionnaire as modified by Kerkhof.
- Participation in an investigational drug or device study within 3 months prior to screening.
- Unwillingness or inability to comply with the study protocol for any other reason.
- People working on nightshifts or regularly fly transatlantic (different time zones) flight.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-08-2014
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO

Date:	29-08-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	NL50063.056.14