The effect of acute moderate alcohol consumption after a psychological stressor on the stress response in men

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Primary objectives: Stress response: To determine whether acute alcohol consumption shortly after a psychological/mental stressor attenuates the stress response recovery.Cholinergic status: To determine whether prolonged moderate alcohol consumption...

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

Summary

ID

NL-OMON32627

Source
ToetsingOnline

Brief title
Effect of acute alcohol consumption after mental tasks

Condition

- Other condition
- Endocrine and glandular disorders NEC
- Immune disorders NEC

Synonym
mental challenge, psychological/mental stress

Health condition

mentale stress

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Alcohol Research
Source(s) of monetary or material Support: Stichting Alcohol Research

Intervention

Keyword: Alcohol, Cholinergic status, Stress

Outcome measures

Primary outcome

Stress response:

Effect of acute alcohol consumption shortly after a psychological/mental

stressor:

- Plasma hormones of the HPA axis (cortisol, ACTH, CRH), and

- Plasma cytokines (TNFα, IL6),

- Endocannabinoids.

Cholinergic status:

Cholinergic status after prolonged moderate alcohol consumption.

Secondary outcome

FAAH activity:

FAAH activity in both adipose tissue and blood after prolonged moderate alcohol

consumption.

Endocannabinoids:

Endocannabinoid and related N-acyl ethanolamine production in adipose tissue

after prolonged moderate alcohol consumption.

Study description

Background summary

It has been proposed that alcohol consumption relieves anxiety and thus may help the individual to cope with stress. Several studies indeed have shown that acute alcohol consumption before a psychological stressor blunts the stress response. However, no data exists on the stress response recovery when alcohol is consumed in moderation shortly after the psychological stressor.

Moderate alcohol consumption has been suggested to suppress chronic low-grade inflammation in adipose tissue. The mechanism appears to involve an increased adiponectin production, but may also be mediated through the endocannabinoid system. Both the stress response and the anti-inflammatory effects may partly be mediated through modulation of the cholinergic status.

Study objective

Primary objectives:
Stress response:
To determine whether acute alcohol consumption shortly after a psychological/mental stressor attenuates the stress response recovery.
Cholinergic status:
To determine whether prolonged moderate alcohol consumption changes the cholinergic status.

Study design

Study design: Randomized, placebo-controlled, open-label crossover trial.

Intervention

Intervention:
Daily consumption of two cans (66 cl) of beer (~26 g alcohol/day) or two cans of non-alcohol beer (66 cl) for two weeks.

Study burden and risks

Subjects need to visit the study site five times during the study period of 29 days (see figure § 11.4). In these visits blood (3x), urine (4x), and adipose tissue (2x) samples will be collected. The total amount collected during the

whole study will be less than 131 mL of blood, ~20 mL of urine, and ~0.6 g of adipose tissue.
The study will be performed in men to prevent influences of the menstrual cycle on stress response and cholinergic status. Cholinergic status comprises both paraoxonase (PON) and cholinesterases (acetylcholinesterase (AChE) and butyrylcholinerase (BChE) activities. Since cholinergic status is subjected to age-dependent changes (1;2), men may not be older than 40 years of age in order to participate with this study.
Based on our previous experiences with alcohol studies with higher daily dosages of alcohol in a similar population for a longer period of time (3;4) (and P8600), we do not foresee any risk associated with participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

9.4 Inclusion criteria
1. Healthy as assessed by the health and lifestyle questionnaire (P8749 F02), physical examination and results of the pre-study laboratory tests
2. Males aged 21-40 years at Day 01 of the study.
3. Body Mass Index (BMI) of 18 - 27 kg/m2.
4. Alcohol consumption >= 5 and <= 28 standard units/week.
5. Normal Dutch eating habits as assessed by P8749 F02.
6. Voluntary participation.
7. Having given written informed consent.
8. Willing to comply with the study procedures, including refrain from drinking alcoholic drinks other then the alcoholic beverage provided by TNO during the entire study.
9. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years.
10. Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned.

Exclusion criteria

9.5 Exclusion criteria
Subjects with one or more of the following characteristics will be excluded from participation:
1. Participation in any clinical trial including blood sampling and/or administration of substances up to 90 days before Day 01 of this study.
2. Participation in any non-invasive clinical trial up to 30 days before Day 01 of this study, including no blood sampling and/or oral, intravenous, inhalatory administration of substances.
3. Having a history of medical or surgical events or disease that may significantly affect the study outcome, particularly psychological disorders or psychiatric, metabolic or endocrine disease and gastrointestinal disorders.
4. Use of medication that may affect the outcome of the study parameters.
5. Having a family history of alcoholism.
6. Smoking.
7. Not having appropriate veins for blood sampling/cannula insertion according to TNO.
8. Reported unexplained weight loss or gain in the month prior to the pre-study screening.
9. Reported slimming or medically prescribed diet.
10. Reported vegan, vegetarian or macrobiotic.
11. Recent blood donation (<1 month prior to the start of the study).
12. Not willing to give up blood donation during the study.
13. Personnel of TNO Quality of Life, their partner and their first and second degree relatives.
14. Not having a general practitioner.
15. Not willing to accept information transfer which concerns participation in the study, or information regarding health, like laboratory results, findings at anamnesis or physical examination and eventual adverse events to and from his general practitioner.

16. Not willing your general practitioner to be notified upon participation in this study

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2010
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	12-01-2010
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL30954.028.09