Effect of moderate alcohol consumption on cephalic phase reflex and gene expression of adipose tissue in postmenopausal women

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Objective: To explore whether 1) acute sensory stimulation in the oral cavity by means of alcoholic beverage (=white wine) induces a cephalic phase reflex (CPR)2) prolonged moderate alcohol consumption affects gene expression pathways of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON32408

Source
ToetsingOnline

Brief title
Effect of alcohol on cephalic phase reflex and gene expression

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
insulin sensitivity, insuline resistance

Research involving
Human

Sponsors and support

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

Intervention

Keyword: alcohol, cephalic phase reflex, gene expression, inflammation

Outcome measures

Primary outcome

Cephalic phase reflex:

Pancreatic polypeptide (PP) in serum.

Gene expression in adipose tissue:

Gene expression pathways related to inflammation, insulin sensitivity

and lipid and carbohydrate metabolism in subcutaneous adipose tissue

Secondary outcome

Markers of inflammation, insulin sensitivity and lipid metabolism:

- Adiponectin (both total and HMW) and cytokines in plasma;

- Cytokines excreted from Peripheral Blood Mononuclear Cells (PBMC)

after

in vitro stimulation with inflammatory agents.

Study description

Background summary

Moderate alcohol consumption has consistently been associated with lowered risk of developing type two diabetes mellitus compared to abstainers and heavy drinkers. However, the underlying mechanism for the lower risk of type two diabetes is not clear.

Study objective

Objective: To explore whether
1) acute sensory stimulation in the oral cavity by means of alcoholic beverage (=white wine) induces a cephalic phase reflex (CPR)
2) prolonged moderate alcohol consumption affects gene expression pathways of inflammatory status, lipid metabolism and insulin sensitivity in adipose tissue in both lean and obese postmenopausal women.

Study design

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

Intervention

Intervention: Daily consumption of 0.25L of dry white wine (12.5% vol.; 25 gram alcohol/day) or 0.25L of water (control) for four weeks.

Study burden and risks

Subjects need to visit the study site nine times during the study period of 57 days (see figure § 11.4). In these visits fasted blood samples (3x), urine samples (8x) and adipose tissue samples from the buttocks (2x) will be collected and body weight measurements (9x) will be performed. The total amount of blood, urine and adipose tissue collected during the whole study will be ca. 35 cL, 32 mL and 600 mg respectively. At each visit, subjects need to fill in a short well-being questionnaire.
The study will be performed in postmenopausal women since previous studies (1) including one of our own (P6689) have demonstrated that this population is more susceptible for alcohol-induced improvements in insulin sensitivity after prolonged moderate alcohol consumption compared to middle aged (2) and young men (3;4) where no such effects were observed in insulin sensitivity after a short alcohol intervention.
Based on our previous alcohol studies using this and other populations for a longer period of time (six weeks; P6689) and higher daily dosages of alcohol (40 gram/day; P5308), we do not foresee any risk associated with participation in this study. (see page 11 P8009)

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

1. Healthy as assessed by the health and lifestyle questionnaire (P8009 F02), physical examination and results of the pre-study laboratory tests
2. Caucasian females aged > 46 and * 65 years at Day 01 of the study.
3. Body Mass Index (BMI) of 18 - 26 or 27 - 35 kg/m2.
4. Postmenopausal as assessed by self reported absence of menstrual periods for at least 12 months.
5. Alcohol consumption >= 5 and <= 22 standard units/week.
6. Normal Dutch eating habits as assessed by P8009 F02.
7. Voluntary participation.
8. Having given written informed consent.
9. Willing to comply with the study procedures, including refrain from drinking alcoholic drinks other then the wine provided by TNO during the entire study.
10. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years.
11. Willing to accept the disclosure of the financial benefit of participation in the study to the authorities concerned.

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 that may significantly affect the study outcome, particularly 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 concerning participation in the study, or information regarding her 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):	12-05-2008
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO
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	NL22794.028.08