Effect of moderate alcohol consumption on postprandial insulin secretion, appetite regulation, glucose homeostasis and insulin resistance.

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Objective: Primary objectives are to study the effects of moderate alcohol consumption on - Postprandial insulin secretion and pancreatic beta-cell function - Physiological and subjective parameters related to satiety and appetiteSecondary…

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

Summary

ID

NL-OMON31093

Source
ToetsingOnline

Brief title
Effect of moderate alcohol consumption on postprandial insulin secretion

Condition

- Other condition

Synonym
- appetite: hunger/satiety

Health condition

insuline secretie en eetlust regulatie

Research involving

Human

Sponsors and support

Primary sponsor: Stichting Alcohol Research
Source(s) of monetary or material Support: Ministerie van OC&W,Opdrachtgever: Stichting Alcohol Research

Intervention

Keyword: alcohol, appetite regulation, insulin secretion, pancreatic beta-cell function

Outcome measures

Primary outcome

Postprandial insulin secretion and pancreatic beta-cell function:

For postprandial insulin secretion main parameters are (i)AUC of glucose,

C-peptides and insulin after a lunch.

Main parameters of pancreatic beta-cell function are glucose sensitivity, rate

sensitivity and potentiation (§ 14.3.3). These parameters can be derived from

mathematical modelling (P7573 B08). C-peptides, glucose and insulin

concentrations will be used as input for the mathematical model.

Physiological and subjective parameters related to satiety and appetite

physiological parameters :of satiety such such as gut hormone concentrations

and endocannabinoids

subjective measuresof satiety such: subjective ratings of appetite and

postprandial wellness (PPW) questions on visual analogue scales (VAS).

Secondary outcome

Miscellaneous markers of glucose homeostasis and insulin sensitivity

Concentrations of miscellaneous markers of glucose homeostasis and insulin

sensitivity, such as HbA1c, fructosamine, apelin, obestatin, visfatin.

Kinetics of alcohol-induced increase in adiponectin

Adiponectin concentrations at baseline and after one, two and three weeks of

treatment.

Gene expression in subcutaneous adipose tissue

mRNA expression of genes corresponding to metabolic pathways involved in

glucose and fatty acid metabolism.

Study description

Background summary

A body of epidemiologic studies shows that moderate alcohol consumption is associated with a protective effect against type 2 diabetes. The importance of both insulin sensitivity and insulin secretion in the pathogenesis of glucose intolerance and diabetes type 2 is widely recognized. Clinical studies show improved insulin sensitivity after a period of alcohol consumption compared to abstention. However, postprandial insulin secretion and beta-cell function after a period of moderate alcohol consumption have scarcely been addressed in published literature.
When consumed as an aperitif or with a meal, alcohol is generally expected to stimulate appetite and food intake and thus might be a risk factor for over consumption and obesity. However the physiological mechanisms for this observed effect are not well understood. Furthermore, previous studies lacked a link between physiological parameters and subjective parameters of satiety.

Previous studies have shown that moderate alcohol consumption improves insulin sensitivity in post menopausal women and other markers of glucose homeostasis, such as HbA1c in young men. Whether these markers also improve in pre menopausal women and whether other markers related to glucose homeostasis also improve after moderate alcohol consumption is unknown.
Adiponectin is an adipose tissue-derived protein. Low levels are associated with obesity, insulin resistance and type 2 diabetes. Several clinical studies show an increase in adiponectin concentrations after a period

of moderate alcohol consumption. However, there is little knowledge about the kinetics of alcohol-induced increases of adiponectin.
It has been shown that diet intervention studies are powerful enough to trigger significant differences in gene expression of adipose tissue. These intervention studies have the power to reveal important signalling pathways involved in glucose and fatty acid metabolism. There is little knowledge on whether moderate alcohol consumption changes gene expression of these pathways.

Study objective

Objective:
Primary objectives are to study the effects of moderate alcohol consumption on
- Postprandial insulin secretion and pancreatic beta-cell function
- Physiological and subjective parameters related to satiety and appetite
Secondary objectives are to study the effects of moderate alcohol consumption on
- Miscellaneous markers of glucose homeostasis and insulin sensitivity
- Kinetics of alcohol-induced increase of adiponectin
A tertiary objective is to study the effects of moderate alcohol consumption on
- Gene expression in subcutaneous adipose tissue
in normal-weight pre menopausal women with normal fasting plasma glucose.

Study design

Study design: Randomized, partially controlled, open label, cross-over study with a one week wash-out preceding each treatment period

Intervention

Participants will drink daily a test substance for three weeks (2 cans of Amstel beer per day; 66 cL ~ 26 gram alcohol) followed by a reference substance (2 cans of Amstel alcohol-free beer per day; 66 cL < 0.5 gram of alcohol) for three weeks or vice versa. Both treatments are preceded by a one-week wash-out period in which no alcohol is consumed.

Study burden and risks

Subjects need to visit the study site in total 10 times during the study period of 57 days (see figure § 11.4).
The ten visits in study will consist of eight visits for collecting fasted blood samples, body weight measurement and morning urine collection and two visits for a lunch after which several blood samples, appetite and PPW questionnaires on VAS will be taken over a period of time and a fat biopsy from the buttocks. The total amount of blood, urine and fat tissue collected during the whole study will be ca. 522 mL, 50 mL and 600 mg respectively. At each visit, subjects need to fill in a short well-being questionnaire.

According to the knowledge of the author, no studies are published on the effect of moderate alcohol consumption on insulin secretion (or insulin sensitivity) and beta-cell function in pre menopausal women.
The study will be performed in normal-weight pre menopausal women with normal fasting glucose, because young men and women and lean women with a normal fasting glucose show tendencies of increased insulin secretion and improved glucose sensitivity (parameter of beta-cell function) during a meal after moderate alcohol consumption compared to abstention. This study will only be performed in lean women since lean and obese women do not use energy from alcohol with equal efficiency.

To minimize any differences in appetite regulation due to fluctuations in steroid hormones related to the menstrual period and to have a more homogenous group, only women who use oral contraceptives will be included in the study. The two test days on which appetite regulation will be measured are exactly four weeks apart for each person. Therefore, it does not matter in which day of the menstrual cycle the subject is since the treatment is approximately on the same day in the menstrual cycle. Furthermore, plasma concentrations of sex steroid hormones are quite stable during the whole menstrual cycle when using oral contraceptives.
The lunch at TNO will have a fixed size since a laboratory environment may promote over consumption.

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 (P7573 F02; in Dutch), physical examination and results of the pre-study laboratory tests
2. Females between 20 - 44 years of age at day of inclusion
3. Using oral contraceptives for >3 months (only phase 1 or 2 oral contraceptives)
4. Normal fasting glucose levels as indicated by venous fasting plasma glucose levels < 6.1 mmol/L
5. Used to drink beer
6. Alcohol consumption more or equal than 5 and less than 22 glasses/week
7. Body Mass Index (BMI) between 20 and 25 kg/m2
8. Normal Dutch eating habits as assessed by the questionnaire P7573 F02 on health and lifestyle
9. Appropriate veins for blood sampling and cannula insertion
10. Voluntary participation
11. Having given their written informed consent
12. Willing to comply with the study procedures
13. Willing not to serve as blood donor during the study
14. Non restraint eater, defined as a score of < 3.25 in non obese subjects on the Dutch Eating Behaviour Questionnaire
15. Willing to accept use of all nameless data, including publication, and the confidential use and storage of all data for at least 15 years

Exclusion criteria

1. Having the intention to become pregnant, to be pregnant or to lactate during the study
2. Participation in any clinical trial including blood sampling and/or administration of substances up to 90 days before Day 01 of this study
3. Participation in any non-invasive clinical trial up to 30 days before day 01 of the study, including no blood sampling and/or oral, intravenous, inhalatory administration of substances
4. Having a history of medical or surgical events that may significantly affect the study outcome including metabolic or endocrine disease, gastro-intestinal disorder, or eating behavior disorders such as anorexia/bulimia disorders

5. Having a family history of alcoholism
6. Mental or physical status that is incompatible with the proper conduct of the study
7. Use of medication that may affect the outcome of the study parameters (except oral contaceptives)
8. Smoking
9. Reported use of any soft or hard drugs
10. Reported unexplained weight loss or gain of > 3 kg in the month prior to the screen¬ing
11. Reported slimming or medically prescribed diet
12. Reported vegetarian, vegan or macrobiotic
13. Recent blood donation (<1 month prior to the start of the study)
14. Not willing to give up blood donation during the study
16. Not having a general practitioner
17. 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 her general practitioner
18. 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:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-09-2007
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	NL19071.028.07