Valco studie

No registrations found.

Ethical review   Positive opinion
Status   Recruiting
Health condition type -
Study type   Interventional

Summary

ID

NL-OMON22292

Source
Nationaal Trial Register

Brief title
Valco = VochtAfdrijvend effect aLCOhol

Health condition

beer, wine, spirits, diuretic effect

Sponsors and support

Primary sponsor: Wageningen University
Source(s) of monetary or material Support: The European Hydration Institute and The Dutch Beer Institute

Intervention

Outcome measures

Primary outcome

Differences in cumulative fluid balance between the three alcoholic beverages and their non-alcoholic counterparts. In the end conclusions can be drawn on whether or not there is a difference in (cumulative) urine output between beer (beer minus non-alcoholic beer), red wine (red wine minus non-alcoholic red wine) and spirits (spirits (jenever) minus water).

Secondary outcome

Cumulative differences for urinary sodium, potassium and osmolality, comparing the samples before lunch, 1, 2, 3 and 4 hours after lunch and after lunch until the next morning. Urine sodium, potassium and urine osmolality testing is performed to evaluate electrolyte and water balance (status of hydration).

Study description

Background summary

Alcohol consumption is known to increase urine output, which could interfere with normal hydration. This is already recognized as far back as the late sixteenth century, as evidenced by its effects on the Porter in Shakespeare's Macbeth. The underlying mechanism of this effect is possibly due to the inhibition of the release of antidiuretic hormone, vasopressin.

So far, no consistent theory exists on the extent of diuresis by alcohol consumption. A study in rats in 1968 has shown that the diuretic response to alcohol is directly related to alcoholic concentration. This would suggest that strong (distilled) alcoholic beverages may provoke more dehydration than weak alcoholic beverages. On the other hand, Eggleton concluded in 1942 that an additional 100 ml of urine would be produced for each 10 g of alcohol ingested - not mentioning anything about alcohol concentration - though this estimate was based on data from only a single subject. The US Institute of Medicine concluded in 2004 that the effect of alcohol consumption on increasing urine secretion is transient and would not result in appreciable fluid losses. Whereas the European Hydration Institute mention in their key tips on hydration for elderly people specifically something about strong alcoholic beverages: "Strong (distilled) alcoholic beverages may provoke dehydration and are not recommended."

For health communication purposes, specifically towards elderly who have an increased risk of dehydration, it is important to know the exact extent of the diuretic effect of different alcoholic beverages. To the best of our knowledge, no studies have examined the diuretic effect of commercial available weak and strong alcoholic beverages in normal life settings. Only male subjects will be included in this trial to exclude possible impact of hormonal status on fluid balance in women.

Study objective

Objective: To assess the diuretic effect of three standard glasses of beer, red wine and spirits in euhydrated elderly men.

Study design

This study has a cross-over design. The total duration of the study for each participant will be maximal 8 weeks. About two weeks before starting the experiments, a screening will take place, to check whether individuals comply to the in- and exclusion criteria. During the next 6 weeks, subjects will participate in six experimental trials, each separated by a period of at

least seven days.

Beverage types vary between the six trials. Subjects are randomly exposed to: beer (lager), non-alcoholic beer, red wine, non-alcoholic red wine, spirits (jenever) or water. During the test sessions, they will collect urine starting after the first morning urine and the total diet will be provided (same standard diet (and lunch on each test day). The diet will have different levels of energy intake per day, depending on the body weight of the subjects.

During each trial day subjects are not allowed to eat or drink anything but the foods supplied and they should maintain their habitual physical activity pattern. Subjects will consume all foods and drinks at home except for a warm meal in the afternoon that is provided at the research facility. Subjects will consume 3 standard glasses of one of the 6 test beverages within 30 minutes after the meal has started. They will stay for 4 hours after the meal during which they will have to give multiple urine samples (after 1, 2, 3, 4 hours). Also, they have to collect urine from the moment they leave the research facilities until the next morning at home. Before each breakfast, lunch and dinner subjects will have to take one PABA tablet (3 times per day).

Intervention

During each treatment, subjects are randomly exposed to one condition: beer (lager), non-alcoholic beer, red wine, non-alcoholic red wine, spirits (jenever) or water. An amount equal to 30 g of alcohol will be supplied during the beer, red wine and spirits treatment. Fluid will be consumed in 3 equal portions during the first half hour after starting the meal (3*250 ml beer (lager), 3*250 ml non-alcoholic beer, 3*100 ml red wine, 3*100 ml non-alcoholic red wine, 3*35 ml jenever, 3*35 ml water). Only commercially available, unprocessed beverages will be used in this study, to approach practical applicability as much as possible. During each trial day food and fluid intake is controlled.

Contacts

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Eligibility criteria

Inclusion criteria

- Age between 60-75 yrs

- Male gender

- BMI between 20-30 kg/m2

- Normal renal function (normal plasma concentrations of creatinine and urea)

- Used to drink alcoholic beverages

- Healthy (as judged by the participant)

Exclusion criteria

- Usage of an energy restricted diet during the last two months

- Weight loss or weight gain of 5 kg or more during the last two months

- Having endocrine, bowel or neurological disorders that could interfere with outcome variables

- Usage of systemic medication that could interfere with outcome variables (e.g. diuretics)

- Being allergic/intolerant for products under study

- Smoking more than seven cigarettes/cigars per week

- Drinking on average more than 21 alcoholic beverages a week

- Being an alcoholic or history of alcoholism

- Family history of alcoholism (loss of control, tolerance or withdrawal symptoms towards alcohol in direct family)

- Current participation in other scientific research

- Being employee, thesis student or intern of the Division of Human Nutrition (WUR)

Study design

Design

Study type: Interventional

Intervention model: Crossover

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: N/A , unknown

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated):   01-11-2014

Enrollment: 20

Type: Anticipated

Ethics review

Positive opinion

Date: 26-09-2014

Application type: First submission

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
NTR-new	NL4667
NTR-old	NTR4819
Other	: METC-nr: 14/19 (WUR)

Study results