Diuretic action of weak and strong alcoholic beverages in elderly men

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

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

Summary

ID

NL-OMON40979

Source
ToetsingOnline

Brief title
Valco study

Condition

- Other condition

Synonym
Not applicable

Health condition

geen

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: co-financiering door European Hydration

Institute en door het Kennisinstituut Bier,European Hydration Institute,Kennisinstituut Bier

Intervention

Keyword: Beer, Diuretic action, Spirits, Wine

Outcome measures

Primary outcome

The objective of this investigation is to assess the diuretic effect of three

standard glasses of beer, red wine and spirits in euhydrated elderly men.

Secondary outcome

To assess the effect of three standard glasses of beer, red wine and spirits on

urinary osmolality, potassium and sodium levels in euhydrated elderly men.

Study description

Background summary

Alcohol consumption is known to increase urine output, which could interfere with normal hydration. 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. 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.

Study objective

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

Study design

The study has a diet-controlled randomized cross-over design (within subject design) in which participants consume 3 standard glasses of beer, non-alcoholic beer, red wine, non-alcoholic red wine, spirits or water at 6

different test sessions. The order in which participants are exposed to the test beverages is randomized and counterbalanced.

Intervention

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).

Study burden and risks

There is no direct (health-related) benefit for the participant. Three of the 6 test beverages contain alcohol and when consumed these subjects not allowed to leave the research area until their breath alcohol concentration is within the accepted range. Except for the blood sampling for screening (plasma concentrations of creatinine and urea) all functional measurements during the trial (urine volume, urine osmolality, urine sodium, potassium and PABA, body weight and breath alcohol concentrations) are non-invasive and risks are therefore minimal.
During the test sessions, the total diet will be provided (same standard diet and lunch on each test day).
The time investment requested from the participants excluding travel time is in total approximately 30 hours for 18 visits and screening

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

See page 11 of the protocol:
• 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

See page 11 of the protocol:
• 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-10-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	23-09-2014
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL49923.081.14