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Cardiovascular and cutaneous responses to the combination of alcohol and soft drinks: the way to orthostatic intolerance?

Submission date
25/01/2017

Recruitment status
No longer recruiting

Registration date
01/02/2017

Overall study status
Completed

Last Edited
14/02/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Drinking alcohol is common among young people during festive events. Many studies have shown that drinking moderate amounts of alcohol leads to an increase in heart rate and the widening of blood vessels (vasodilation), as well as other issues with blood circulation. When standing upright, gravity means that blood falls towards the feet, and so the body must respond by increasing blood pressure to keep blood flowing to the brain. There is evidence to suggest that drinking alcohol can also interfere with this function (orthostatic hypotension). At festive events, alcohol is usually served with fruit juice or other kinds of sugary drinks. Although the effects of consuming alcohol have been well studied in healthy individuals, there is little research looking at the interaction of sugary drinks with alcohol on the regulation of circulation. The aim of this study is to look at the effects of drinking alcohol when combined with sugary drinks on the circulatory system (heart and blood vessels).

Who can participate?
Healthy adults aged between 18 and 30 who do not smoke.

What does the study involve?
Participants attend four study sessions spaced two days apart in a random order. All sessions take place between 08:00 and 09:00 in the laboratory after 12 hours of not having eaten. Before each session (at around 07:00), participants eat a light breakfast provided by the research team which consists of light ice tea and two cereal bars. They then complete a standing test before drinking either water missed with lemon juice (condition 1), sugar and lemon juice mixed with water (condition 2), 40% vodka missed with lemon juice and water (condition 3) or 40% vodka mixed with sugar, water and lemon juice (condition 4). Participants have their blood pressure monitored continuously for 120 minutes after drinking each drink.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
University of Fribourg (Switzerland)

When is the study starting and how long is it expected to run for?
March 2015 to October 2016

Who is funding the study?
University of Fribourg (Switzerland)

Who is the main contact?
Dr Claire Maufrias

Contact information

Type(s)
Scientific

Contact name
Dr Claire Maufrais

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Alcopops

Study information

Scientific Title
Acute ingestion of sugar and alcohol in healthy young people: the way to orthostatic hypotension?

Study objectives
The vasodilatory properties of alcohol and the alcohol-induced dysregulation of autonomic tone are potentiated by the concomitant ingestion of sugary drinks in young people (simulating

alcopops ingestion), and thus that the combination of sugars with alcohol will accentuate the systemic vasodilation and increase orthostatic intolerance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Commission cantonale d'éthique de la recherche sur l'être humain (CER-VD), 28/04/2015, ref: 105 /15

Study design
Randomised cross over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute alcohol ingestion in young people

Interventions
All participants attend four separate experimental sessions (each session separated at least by 2 days) according to a randomized crossover study. Randomization is performed using a random sequence generator (http://www.random.org/sequences/) where the session order is determined for 24 test subjects before the study starts.

All experiments take place in a quiet, temperature-controlled (20–22 °C) laboratory and started between 08.00 and 09.00 A.M. On the day of the experiment, after an overnight (12-h) fast, participants eat a light standardized breakfast provided provided by the research team at around 07:00, consisting of one mini-pack of 33 cl of commercial light ice tea (33 kcal, 8 g carbohydrates/6.6 g sugar) and two cereal bars (total of 150 kcal, 39 g carbohydrates/12 g sugar), to ensure that consumption of alcohol in the same morning is done on an empty stomach.

Following a variable period for reaching cardiovascular and metabolic stability (usually between 10-15 minutes), and after a stable baseline recording of at least 30 minutes, participants undergo an orthostatic test consisting of active standing from the sitting position, maintained during 10 min, and then returning to a sitting position. Participants then ingest one of the following four drinks at a temperature of around 10°C (at a convenient pace over 5 min):

1. 390 mL distilled water + 10 mL lemon juice
2. 48 g sucrose + 10 mL lemon juice, diluted in distilled water up to a total volume of 400 mL
3. 40% vodka (40% alcohol per volume, given at 1.28 mL.kg-1 of body weight, providing 0.5 g alcohol/kg) + 10 mL lemon juice, diluted in distilled water up to 400 mL
4. 48 g sucrose + 40% vodka (at 1.28 mL.kg-1) + 10 mL lemon juice, diluted in distilled water up to 400 mL.

Hemodynamic monitoring continues for another 130 minutes post-drink ingestion with a 10 min orthostatic test at 60 and 120 min post-drink ingestion.

Intervention Type

Primary outcome measure
Blood pressure is measured using a task force monitor at baseline and averaged over these different timepoints post-ingestion: 0-10min, 10-20min, 20-40min, 40-60min and 100-120min

Secondary outcome measures
Vasodilation was calculated using task force monitor (i.e. total peripheral resistance) and estimated using thermographic pictures (hand temperature) at baseline and averaged over these different timepoints post-ingestion: 0-10min, 10-20min, 20-40min, 40-60min and 100-120min.

Overall study start date
01/03/2015

Completion date
01/10/2016

Eligibility

Key inclusion criteria
1. Aged 18-30 years
2. Non-smokers
3. No disease or medication affecting cardiovascular or autonomic regulation

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
30 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. BMI greater than 30 kg.m-2
2. Competition athletes
3. Individuals with a daily exercise workload exceeding 60 min per day

Date of first enrolment
01/02/2016

Date of final enrolment
15/09/2016

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Fribourg
Department of Medicine/Physiology
Chemin du musee 5
Fribourg
Switzerland
1700

Sponsor information

Organisation
University of Fribourg

Sponsor details
Chemin du musee 5
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Sponsor type
University/education

ROR
https://ror.org/022fs9h90

Funder(s)

Funder type
University/education

Funder Name
University of Fribourg

Alternative Name(s)
Universität Freiburg, University of Fribourg

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal before September 2017.

Intention to publish date
01/09/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Claire Maufrais (claire.maufrais@hotmail.com)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		31/01/2016	14/02/2017	No	No