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

Recruitment status	<ul><li>Prospectively registered</li></ul>		
No longer recruiting	∐ Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category	[] Individual participant data		
	No longer recruiting  Overall study status  Completed		

# 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

#### **ORCID ID**

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#### Contact details

University of Fribourg Chemin du musee 5 Fribourg Switzerland 1700

# Additional identifiers

# Protocol serial number

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

# Study type(s)

Prevention

# 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(s)

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

# Key secondary outcome(s))

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.

# 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

# Healthy volunteers allowed

No

# Age group

Adult

#### Lower age limit

18 years

# Upper age limit

30 years

#### Sex

All

# 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

#### **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**

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes