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When drinking water to prevent fainting, does the temperature matter?

Submission date
04/11/2021

Recruitment status
No longer recruiting

Registration date
14/12/2021

Overall study status
Completed

Last Edited
18/07/2022

Condition category
Other

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

Plain English Summary
Background and study aims
The aim of this study is to determine whether drinking water can improve orthostatic tolerance in healthy control volunteers. Orthostatic tolerance refers to the ability to maintain adequate blood pressure when standing. In some people blood pressure can fall when standing, which can lead to dizzy spells or fainting episodes. Drinking water can boost blood pressure and make fainting episodes less likely to occur. However, it is not clear whether the temperature of the water has an impact on the blood pressure response. This study will test whether warm water and cold water have the same effect on blood pressure responses.

Who can participate?
Healthy English-speaking men and women aged 19-50 years

What does the study involve?
Participants will be asked to undergo a “tilt test”. This test measures blood pressure control and susceptibility to fainting spells. Participants will undergo this test on three separate days. On each day they will be given a drink of water: either a 500 ml drink of room temperature water, a 500 ml drink of ice-cold water, or a 500 ml drink of warm water. The order in which they receive the water will be determined randomly.
Before the start of the test one of the study team will ask participants some questions about their medical history and their general health. There will also be questions about heart disease risk factors such as smoking, exercise levels, and alcohol consumption. They will measure the participants' height and weight. Participants will be asked to empty their bladder before testing. The researchers will take a urine measurement of the amount of salt in the urine – a marker of salt intake and hydration.
For the test procedure, participants will be asked to lie down on a bed while we attach monitoring equipment to their body. This will include:
1. An electrocardiogram (ECG). This is a monitor that will measure their heart beat (how fast and how regularly the heart is beating). The researchers will attach three adhesive electrodes (stickers) to the skin of the participant's chest and connect them to the ECG machine. If participants have a hairy chest, it may be necessary to shave three small areas of their chest in order to help the electrodes stick to their skin. An alcohol swab will be used to clean the skin before electrode placement.

2. A blood pressure monitor. A small Velcro cuff will be placed around the middle finger that pulses gently against the small arteries along the side of the finger and records their blood pressure with every heartbeat. This measurement is non-invasive and painless.
3. The researchers will measure breathing rate and the gases in the air the participants are breathing out with a small nasal cannula (a flexible tube). This small plastic tube will be placed under their nose, on their top lip, and will sample their breathing. Participants will be able to breathe and talk normally while wearing this device.
4. The researchers will measure the blood flow to the brain in an artery called the middle cerebral artery. They will do this using ultrasound (imaging device). They will place a little ultrasound gel on the temple and will position an ultrasound probe overlying the gel. The probe will be held in place with a headband. This means the investigators will not need to touch the participant to hold the probe. Participants can move their head freely when wearing the ultrasound probe. They will not be able to feel the ultrasound.
5. The researchers will also measure blood flow in the arm, in the brachial artery, also with ultrasound. The participant's arm will be placed on a support with a probe positioned over a little ultrasound gel near the elbow. Participants will be asked to keep their arm still during the test.
6. The researchers will place a strap over the participant's knees and a box over their legs that seals against their waist (a bit like a canoe skirt). The strap is to help them stand in a relaxed position without fidgeting their legs too much. The box is placed over their legs so that they can apply lower body negative pressure to their legs later on in the test without disturbing the monitoring.
Once the monitors are in place the researchers will make recordings from them for 15 minutes while they lie on your back and rest. Participants will then be given the water to drink. After a further 15 minutes of resting, they will tilt the table into an upright position (at 60 degrees). This is like standing but leaning backwards slightly. The researchers will make recordings from the monitors for a further 20 minutes. They will ask participants not to move their legs much during the test. After 20 minutes of standing, they will apply lower body negative pressure to the box over their legs. This will feel a little bit draughty, and may be a little noisy, but is not painful or unpleasant. The effect mimics prolonged standing. The researchers will apply the lower body negative pressure at three different levels for 10 minutes each (-20 mmHg, -40 mmHg and -60 mmHg).
The test will be stopped immediately if:
1. Participants complete the whole procedure (30 minutes lying down, 20 minutes standing, and 30 minutes of lower body negative pressure).
2. They experience symptoms of dizziness or lightheadedness and/or their blood pressure or heart rate begin to decrease.
3. They request the test to stop.
Participants will then be returned to the lying position. If they experience dizziness at the end of the test, lying down will quickly resolve this. The monitors will be removed and any residue from the ultrasound gel will be removed. It is common to feel a bit hot and sweaty at the end of the test. There are showers near to the lab, and the researchers can provide clean towels etc for participants to freshen up after the test if they wish.

What are the possible benefits and risks of participating:
There are no direct benefits to participants. It is hoped that the results of this study will ultimately aid in the treatment and management of fainting spells in patients who are prone to these episodes, and so improve quality of life for those affected by recurrent fainting episodes.
Participants will receive up to $75 to compensate you for your participation in the study ($25 per test). Free parking is available on request.

What are the potential disadvantages to taking part?
The study will take place in a controlled laboratory environment and most participants do not find the assessments unpleasant. Every effort will be made to ensure their safety, privacy and comfort. The following are discomforts or risks that may be associated with the procedures.
1. During the tilt table test participants may experience some dizziness or lightheadedness associated with reduced blood pressure and/or heart rates. Rarely, participants have been known to faint briefly. Actual fainting is unusual and is always very short in duration with rapid return to consciousness.
2. These assessments will take time to perform and participants will be asked to keep still during the assessments. They may find that they become uncomfortable or bored during the course of these investigations. Every effort will be made to maintain their comfort throughout the study. Participants will be provided with pillows, blankets etc as appropriate to ensure their comfort. To compensate them for their time, participants will be paid $25 for each of the three tests that they complete.
3. Preparing the skin for electrode placement may cause minor irritation or redness. It is possible that participants will experience an allergic reaction to the electrode gel or adhesive.

Where is the study run from?
The study is a collaborative effort between Simon Fraser University (Canada) and King's College London (UK). It will be run from the Department of Biomedical Physiology at Simon Fraser University.

When is the study starting and how long is it expected to run for?
December 2018 to October 2019

Who is funding the study?
National Sciences and Engineering Research Council of Canada (NSERC) (Canada)

Who is the main contact?
Prof. Victoria Claydon
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019s0224

Study information

Scientific Title
The effect of water temperature on orthostatic tolerance

Study hypothesis
1. The cold-water condition would attenuate the deterioration of cardiovascular and cerebrovascular stability during orthostatic stress and increase OT (time to presyncope) in comparison to bolus water drinking at room temperature
2. The warm water condition would exacerbate the deterioration of cardiovascular and cerebrovascular stability during orthostatic stress and decrease OT in comparison to bolus water drinking at room temperature.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 16/07/2019, Simon Fraser University Research and Ethics Committee (Office of Research Ethics, Simon Fraser University, 8900 Nelson Way, Burnaby, BC, V5A 4W9, Canada; +1 (0)778 7823 447; dore@sfu.ca), ref: 2019s0224

Study design
Single-blind randomized cross over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

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

Condition
Prevention of vasovagal syncope in patients with orthostatic intolerance

Interventions
Participants were randomised, in single-blind crossover fashion, to either a 500 ml drink of room temperature water, which was the control condition (20°C) (ROOM), a 500 ml drink of ice-cold water (0-3°C) (COLD), or a 500 ml drink of warm water (45°C) (WARM). Each intervention was applied on a different day, with a single day testing and endpoint (3 x one day).

Intervention Type
Behavioural

Primary outcome measure
Orthostatic tolerance measured by time to presyncope following the head-up tilt test and subsequent progressive lower body negative pressure. Each intervention was applied on a different day, with a single day testing and endpoint (3 x one day).

Secondary outcome measures
Each intervention was applied on a different day, with a single day testing and endpoint (3 x one day):
1. Cardiovascular stability measured by Finometer, echocardiography and forearm ultrasound Doppler following the head-up tilt test and subsequent progressive lower body negative pressure
2. Cerebrovascular stability measured by middle cerebral artery ultrasound Doppler following the head-up tilt test and subsequent progressive lower body negative pressure

Overall study start date
01/12/2018

Overall study end date
01/10/2019

Eligibility

Participant inclusion criteria
Healthy volunteers 19-50 years of age

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
18

Total final enrolment
17

Participant exclusion criteria
1. <19 or >50 years old
2. Pregnant
3. Trying to conceive
4. Prior history of cardiovascular or neurological disease

Recruitment start date
16/07/2019

Recruitment end date
30/09/2019

Locations

Countries of recruitment
Canada

Study participating centre
Simon Fraser University
Department of Biomedical Physiology
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/0213rcc28

Funder(s)

Funder type
Research council

Funder Name
Natural Sciences and Engineering Research Council of Canada (Discovery RGPIN/02982-2021 and Discovery Accelerator Supplement RGPAS/2021-00012-2021).

Alternative Name(s)
Conseil de Recherches en Sciences Naturelles et en Génie du Canada, NSERC, CRSNG

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Ministry of Defence

Alternative Name(s)
Ministry of Defence, Government of India, Ministry of Defence, Govt. of India, Indian Ministry of Defence, Raksha Mantralay, MOD

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
India

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/04/2022

Individual participant data (IPD) sharing plan
An anonymised dataset is available from Prof. V Claydon (Victoria_claydon@sfu.ca) upon reasonable request. This will include the raw cardiovascular and cerebrovascular data. This will be available for 2 years following the peer-reviewed publication of the results. The data will be available for the purposes of academic endeavour only for the purposes of meta-analysis following agreement by participants.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	27/02/2019	05/11/2021	No	No
Results article		01/04/2022	18/07/2022	Yes	No