ISRCTN13778462 https://doi.org/10.1186/ISRCTN13778462

How do needle pokes affect fainting susceptibility?

Submission date
28/09/2022

Recruitment status
No longer recruiting

Registration date
04/11/2022

Overall study status
Completed

Last Edited
05/12/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
The primary purpose of this study is to determine how placing a needle in a vein affects susceptibility to fainting in healthy people. In some people blood pressure can fall when standing, causing dizzy spells or fainting. Fainting is also common in volunteers for blood donation, as well as during blood tests, dental care and injections. This can deter people from giving blood or undergoing medical procedures. The main goal of this study is to investigate why some people faint with needles, by testing how blood pressure control is affected by the placement of a needle in a vein when we use three different types of anesthetic (numbing) cream (on three different days).

Who can participate?
Healthy English-speaking people aged 16-50 years

What does the study involve?
Before you start, one of the study team will ask you some questions about your medical history, medication use, and your general health. There will also be questions about cardiovascular risk factors such as smoking, exercise levels, and alcohol consumption. They will measure your height and weight.
On each test day you will be asked to undergo a “tilt test”. This test measures your blood pressure control and your susceptibility to fainting spells. You will undergo this test on three separate days. On each day the testing will take about 3 hours to complete, so the whole study will take about 9 hours. On each day we will put a different type of anesthetic (numbing) cream on your hand and forearm and cover it with a dressing. The amount of numbing may be different between the numbing creams. Once the numbing cream is applied you can relax, read, work on a computer etc for about one hour while the medication takes effect.
You will then be asked to provide a urine sample so we can measure how well hydrated you are, and how much salt is in your urine.
You will then be asked to fill in three questionnaires. These questionnaires will assess your background level of anxiety as well as fears associated with blood and medical procedures.
For the tilt test procedure, you will be asked to lie down on a bed while we attach monitoring equipment to your body. This will include:
1. An electrocardiogram (ECG). This is a monitor that will measure your heartbeat. We will put

three adhesive electrodes (stickers) on the skin of your chest (on your left and right shoulder, and the left side of your belly button) and connect them to the ECG machine. If you have a hairy chest, we may need to shave three small areas of your chest to help the electrodes stick to your skin.
2. A blood pressure monitor. A small Velcro cuff will be placed around your middle finger that pulses gently against the small arteries along the side of the finger, and records your blood pressure with every heartbeat. This measurement is non-invasive and painless.
3. We will measure your breathing rate and the gases in the air you breathe out with a small flexible plastic tube placed under your nose, on your top lip. You will be able to breathe and talk normally while wearing this device.
4. We will measure the blood flow in one of the arteries in your brain using ultrasound (imaging device). We will position an ultrasound probe on some gel on your temple and hold it in place with a headband. This means the investigators will not need to touch you to hold the probe. You can move your head when wearing the ultrasound probe. You will not be able to feel the ultrasound.
5. We will also measure blood flow in your arm with another ultrasound probe positioned over some ultrasound gel near the elbow. We will ask you to keep your arm still during the test.
6. We will place a strap over your knees and a box over your legs that seals against your waist (a bit like a canoe skirt). The strap is to help you stand still without fidgeting your legs too much.
Once the monitors are in place we will make recordings from them for 15 minutes while you lie on your back and rest. We will then place an intravenous cannula (an IV; a small tube that sits in a vein) at one of the sites where the cream was applied. You will be asked to look away while we do this, and we will place a screen in the way so you can't accidentally see the needle going into your body. This is because the sight of the needle might change your blood pressure. As with any procedure involving needles, you might feel some discomfort when the needle is placed in the skin, but because of the numbing cream it might be less than usual. Once it is in place the cannula will be covered with a bandage to make sure it stays in place during the test.
Following cannulation we will tilt the table into an upright position. We will make recordings from the monitors for a further 20 minutes. We will ask you not to move your legs much during the test. After 20 minutes of standing, we will remove some of the air from the box over your legs. This will feel a little bit drafty, and may be a little noisy, but is not painful or unpleasant. The effect mimics prolonged standing. We will do this at three different levels for 10 minutes each.
The test will be stopped immediately if:
1. You complete the whole procedure (about 20 minutes lying down, 20 minutes standing, and 30 minutes standing with the air being removed from the box).
2. You experience symptoms of dizziness or lightheadedness and/or your blood pressure or heart rate begins to decrease.
3. You request the test to stop.
You will then be returned to the lying down position. If you experienced dizziness at the end of the test, lying down will quickly resolve this. The monitors will be removed, the cannula will be removed and a band-aid placed over the site where the needle went into your skin, 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 we can provide clean towels etc for you to freshen up if you wish.

What are the possible benefits and risks of participating?
There are no direct benefits to you from taking part in the study. It is hoped that the study results will help us understand why some people faint, improve retention for blood donors and facilitate blood sampling in needle fainters. You will receive up to $75 to compensate you for your participation ($25 each time you attend the laboratory). If you decide to stop the study part way through you will be compensated for each test that you attended. Free parking is available

on request.
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 your safety, privacy and comfort. The following are discomforts or risks that may be associated with your procedures.
1. During the tilt table test or IV cannulation you may experience some dizziness or light-headedness 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 a rapid return to consciousness.
2. These assessments will take time to perform and you will be asked to keep still during the assessments. You may find that you become uncomfortable or bored during the tests. Every effort will be made to maintain your comfort throughout the study. You will be provided with pillows, blankets etc as appropriate to ensure your comfort. To compensate you for your time, you will be paid $25 for each of the three tests that you complete.
3. Preparing the skin for electrode placement may cause minor irritation or redness. It is possible that you will experience an allergic reaction to the electrode gel or adhesive.
4. The cannula insertion, despite the numbing cream, can sting and/or be painful during insertion and for a few hours after the numbing cream has worn off. Sometimes it may result in complications including nerve damage, bruising, arterial puncture and clot formation. Any intravenous procedure has a theoretical risk of infection. The technique will be performed by a medical doctor or research nurse who is skilled in this procedure.
5. The topical numbing creams can cause transient skin colour changes, redness, itching, burning or the sensation of skin hot/coldness. Very rarely (<1%) participants can be allergic to one of the creams which can cause a more severe reaction. You should not take part in the study if you know you are allergic to the medications in the numbing cream. If you have an allergic response to the numbing cream the study medical doctor or research nurse will treat it if necessary.

Where is the study run from?
Simon Fraser University (Canada)

When is the study starting and how long is it expected to run for?
January 2020 to January 2023

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

Who is the main contact?
Dr Victoria Claydon, victoria_claydon@sfu.ca

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2020s0054

Study information

Scientific Title
The effect of intravenous cannulation on orthostatic tolerance

Study objectives

It is hypothesized that the application of a topical anesthetic will mitigate the discomfort associated with intravenous cannulation and will reduce the impact of intravenous cannulation on orthostatic tolerance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/02/2020, Simon Fraser University Office of Research Ethics (8900 Nelson Way, Burnaby, BC, Canada; +1 (0)778 782 3447; dore@sfu.ca), ref: 20200054

Study design
Single-center randomized double-blinded interventional cross over trial. Note that this study employs deception

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

Health condition(s) or problem(s) studied
Vasovagal syncope

Interventions
Volunteers will be asked to undergo a “tilt test” to assess cardiovascular reflex control and orthostatic tolerance (measured as time to presyncope, or near fainting, in minutes). We and others have previously shown this technique to be reproducible, reliable, and to have high sensitivity and specificity for differentiating persons with differing orthostatic tolerance, or for examining the effects of interventions aimed at improving orthostatic tolerance.

Volunteers will undergo this test on three separate days where they will be randomised to three different exposures. These exposures involve IV procedures with different topical anesthetics and deception. Both the participant and the person responsible for terminating the test will be blinded to the study condition, and therefore the study will be double-blinded. To ensure a similar number of participants were exposed to each possible intervention order (six possible allocation orders), randomization was blocked.

Intervention Type
Other

Primary outcome measure
Orthostatic tolerance in minutes, determined using a head-upright tilt test with combined lower body negative pressure. Orthostatic tolerance is a measure of fainting susceptibility and represents the time it takes from tilt test initiation, to the time at which a significant drop in blood pressure is observed, consistent with a pre-syncopal (near-fainting) response. Measured on three separate days after each of the three different exposures.

Secondary outcome measures
1. Sodium levels (a marker of salt intake and hydration) measured using a urine sample before the tilt test

Measures of cardiovascular reflex control recorded continuously and non-invasively at baseline and throughout the tilt test:
2. Heart rate measured using a standard three-lead ECG
3. Beat-to-beat blood pressure will be determined using the Finometer blood pressure monitoring device. This consists of a small Velcro cuff placed around the middle finger that pulses gently against the digital arteries and records and displays blood pressure with every heartbeat.
4. Any influence of possible hyperventilation and the associated decreases in carbon dioxide on cerebral blood flow, evaluated using end tidal gases sampled using a nasal cannula
5. Cerebral blood flow determined in the middle cerebral artery using Doppler ultrasound. An ultrasound probe will be positioned on the skin overlying the temple and held in place with a headband. Participants can move their heads freely when wearing the ultrasound probe.
6. Blood flow in the brachial artery, measured with ultrasound. The arm will be placed on a support with a probe positioned over a little ultrasound gel near the elbow.

Overall study start date
01/01/2020

Completion date
30/01/2023

Eligibility

Key inclusion criteria
1. Healthy, English-speaking men and women aged 16-50 years
2. In order to reduce the likelihood of transmission of COVID-19, participants are only eligible to participate in the study if they have received full immunisation against COVID-19 according to current Health Canada guidelines. Accordingly, participants will be asked to provide evidence of their vaccination status in order to take part in the study.

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
16 Years

Upper age limit
50 Years

Sex
Both

Target number of participants
28

Total final enrolment
30

Key exclusion criteria
1. Women will be excluded if they are pregnant, or think they might be
2. Participants who self-identify as having cardiovascular or neurological disease will be excluded from the study, as these factors may influence the outcome of the study
3. Individuals who suffer from recurrent fainting episodes (≥2 episodes of syncope in the prior 6 months) will be excluded
4. Contraindications to EMLA anesthetic cream: previous diagnoses of liver disease, methemoglobinemia or GP6D deficiency; known allergy to lidocaine or prilocaine; breastfeeding; pregnancy. Out of an abundance of caution and given the known potential interactions between certain medications and EMLA, participants taking any prescription medications will be excluded (with the exception of hormonal contraceptives).

Date of first enrolment
01/03/2020

Date of final enrolment
30/05/2022

Locations

Countries of recruitment
Canada

Study participating centre
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Cardiovascular Physiology Laboratory
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Funder(s)

Funder type
Government

Funder Name
Natural Sciences and Engineering Research Council of Canada

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

Results and Publications

Publication and dissemination plan
The researchers plan to publish this study in a high-impact peer-reviewed journal and present these findings at national and international conferences in the field of research.

Intention to publish date
31/12/2023

Individual participant data (IPD) sharing plan
Due to legal and ethical restrictions, data cannot be made publicly available. Data will be made available upon request from the primary investigator Victoria Claydon (victoria_claydon @sfu.ca). Additional published or public analyses would only be permitted with ethics approval for secondary data access.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/08/2023	05/12/2023	Yes	No