

Participant Information Sheet- Civilians

Study Title: The investigation of drink supplements to decrease fainting

MoDREC Application No: 962/MODREC/19

Invitation to Take Part

We would like to invite you to take part in a research study looking at ways to increase the water content in blood.

Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Feel free to ask us, (in person or by phone or email) if you would like more information or if there is anything that you do not understand.

We are looking for volunteers who are between 18 and 50 years.

If you are prepared to volunteer, you would be required to attend King's College Hospital. You will not have to stay overnight.

What is the Purpose of the Research?

The purpose of this research is to determine if a mix of different supplements can improve your ability to be able to stand upright for long periods of time and reduce the chance of fainting in people who are prone to fainting.

It does this by supporting the blood pressure. Blood pressure can fall when standing, predisposing to dizzy spells or fainting episodes. Some supplements that you can buy over the counter can boost blood pressure and make fainting episodes less likely to occur. One of these is simple table salt. However, it is not clear whether a mix of different supplements has a greater effect than salt by itself.

Who is Doing This Research?

This study has been funded by the London District of the British Army and is being conducted with King's College London University. There is a team of researchers directly involved in the work as well as others assisting. One of these is a British Army Doctor, the others are civilian medical doctors, scientists or nurses. The research is part of a PhD (University Degree) project.

Why Have I Been Invited to Take Part?

You have been invited to take part because you are local to King's College Hospital. You may have also previously fainted or feel as though you are prone to fainting. You have shown to us that you are interested in participating by contacting the research team.

Do I Have to Take Part?

No, participation is entirely voluntary. Not taking part will have no effect on you.

What Will I Be Asked to Do?

You will travel to **MRI 2 (ground floor) King's College Hospital, Denmark Hill, Brixton, London SE5 9RS**. You will be asked to attend in comfortable clothes. You will be asked not to drink alcohol the night before the test and until all testing has been completed (approximately 10 days). You will not be required to stay overnight at the hospital. The study will not run later than 1730.

You will be asked to attend King's College Hospital for two days of testing. Following this you will be asked to take a supplement twice a day for a week. Following taking the supplement at home for 7 days you will be requested to attend the Clinical Research Facility again for a further two days. We will then repeat the investigations we did in days 1 and 2. The entire study will take no more than 11 days of which you will only need to attend the King's College Hospital for 4 days.

Day 1

Tests will usually be conducted in the mornings. Please have a light breakfast before arriving and avoid caffeine (coffee, tea, red bull etc) before coming. Please also avoid exercise for 12 hours prior to testing.

Before you start the test one of the study team will ask you some questions about your medical history, and your general health. Occasionally, if you have had significant previous medical problems, we will be unable to continue testing in you. If you are fit and healthy, but not a competing athlete, this is unlikely. We will then ask you to empty your bladder and perform some measurements on your urine.

You will be asked to undergo a "tilt test" (see below). This test measures your blood pressure control, and your susceptibility to fainting spells. You will undergo this test on the first day. If we find that you are **very resilient to fainting you will not be required to undergo any further testing**. This is because we do not think the supplements will have much effect on you.

For the tilt test procedure, you will be asked to lie down on a bed while we attach monitoring equipment to your body. You can choose to go topless or wear a hospital style gown. This will include:

1. An electrocardiogram (ECG). This is a monitor that will measure your heart beat (how fast and how regularly your heart is beating). We will attach three stickers to the skin of your chest and connect them to the ECG machine. If you have a hairy chest, it may be necessary to shave three small areas of your chest in order to help the stickers to stick to your skin. An alcohol swab will be used to clean the skin before placement.
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 can make your fingertip go a bit numb after a while but is otherwise painless.
3. We will take some ultrasound measurements of your heart to get another measure of the amount of blood leaving your heart with each heartbeat. This will not be done continuously but on occasion throughout the test.
4. 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 in a relaxed position without fidgeting your legs too much. The box is placed over your legs so that we can apply lower body negative pressure to your legs later on in the test without disturbing the monitoring.

Once the monitors are in place we will make recordings from them for 15 minutes while you lie on your back and rest. a further 15 minutes of resting, we will tilt the table into an upright position (at 60 degrees). This is like standing, but leaning backwards slightly. 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 apply lower body negative pressure to the box over your legs. This will feel a little bit draughty, but is not painful or unpleasant. The effect mimics prolonged standing. We will apply the lower body negative pressure at three different levels for 10 minutes each.

The test will be stopped immediately if:

- You complete the whole procedure (30 minutes lying down, 20 minutes standing, and 30 minutes of lower body negative pressure).
- You experience symptoms of dizziness or lightheadedness and/or your blood pressure or heart rate begin to decrease.
- You request the test to stop.

You will then be returned to the flat (supine) position. If you experienced 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.

If you are not particularly resilient to the tilt test we will give you a 24 hour urine collection pot. This is a sealed plastic canister. Following completion of the test we will ask that you only urinate in this pot (ie not use the toilet). We will ask that you return the pot the following day when you undergo day two testing.

If you are resilient to the tilt test we will be unable to perform any further testing.

Day 2

On day 2 you will return your 24 hour urine collection bottle to us. We will measure your body composition using a special type of scale that gives us your muscle, fat and water mass too. We will also take some measures of blood pressure and your heart rhythm with an ECG. We will also do an ultrasound scan of your heart (echocardiogram). You will be asked to remove any clothing on their upper body. They can choose to complete the testing bare chested, or to change, in privacy, into a hospital gown.

We will also take some blood where we will look at your ability to handle salt and the amount of water in your blood. We will also assess whether you have previously been infected with COVID-19 as this may influence your "tilt test".

Day 3 to Day 9

Following this you will be asked to take a supplement twice a day for a week. The supplement will be provided in a powder and liquid form. The supplement is legal. The powder will come in 14 small bags. The liquid will come in 14 small bottles. We will give you extra in case you spill some. We will also give you one large sports bottle (1L).

In the morning after waking we will ask you to:

1. Pour the powder into the sports bottle.
2. Pour the small bottle into the large (1L) bottle on top of the powder
3. Fill the bottle up completely (with 1L of water)
4. Drink the contents as quickly as comfortably possible (ideally within 30 minutes)

We will ask you to repeat these steps again at lunchtime.

In case you are unable to make your next appointment with us we will give you some spare sachets of powder and spare small bottles. Please continue to make the drinks up until we see you again. If you run out let us know and we can provide you with some more. If you experience side effects please let us know and we will instruct you further. You may still be able to continue with the study if you so desire.

Day 10

On day 10 you will return to King's College Hospital. There is no need to make up the drink the morning prior to attending. We will do this for you when you arrive as it is important you take the drink on the day. We will then repeat the tilt test. We will again give you a 24 hour urine bottle which we will ask you to urinate in exclusively for the next 24 hours.

Day 11

On day 11 we will repeat the blood tests, ultrasound of your heart, ECG, blood pressure and body composition measures.

If you wish to take part you are to email the main researcher:

iain.parsons@kcl.ac.uk

Should you wish to take part, the study team will arrange a date for you to attend King's College Hospital. When you arrive at King's College Hospital members of the study team will meet you. They will explain again what you will be required to do. They will answer any questions that you may have. If you are then happy to volunteer to take part in the study you will be asked to sign a consent form.

You should NOT volunteer for the study if you are:

1. A professional athlete that requires to submit blood tests to the World Anti-Doping Organisations (WADA). This is only relevant for people who compete at National or International level of sport or plan to compete in the next 3 months. This is not relevant for subjects who compete in club or university level sports. This is because WADA have very strict rules on supplements to ensure a level playing field in professional sports.
2. Regularly taking sports supplements in the last 3 months- as this could interfere with our results.
3. You are pregnant or are currently trying to become pregnant.
4. You are diabetic.
5. You have heart failure.

Processed samples of blood may be frozen and stored at King's College Hospital. All the samples will be labelled with a number. They will be anonymised and you will not be identifiable from them. We can then make the measurements altogether in a batch at the end once we have collected enough samples from several volunteers. The samples will be destroyed within two years. Unused samples will be disposed of through approved procedures for clinical waste.

What is the Device or Procedure That is Being Tested?

We are testing what mix of supplements increase your ability to stand for prolonged periods of time.

What are the Benefits of Taking Part?

None directly to you.

What are the Possible Disadvantages and Risks of 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 your safety, privacy and comfort. The following are discomforts or risks that may be associated with your procedures.

1. During the tilt table test you 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. The procedure itself though is very safe.
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 course of these investigations. 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.
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. You will be asked to perform two blood tests.
5. You will be asked to collect your urine for 24 hours twice. This can be a little inconvenient, particularly for women, as it means you need to urinate in a cannister only.
6. You are not to drink alcohol during the course of the study as this can interfere with the results. We will also request that you don't start taking any other exercise supplements. Other than this, we would ask you to not do anything that you wouldn't normally do.
7. Rarely you may also be found to have an incidental medical condition. These will be communicated to you in full. See **Will My Taking Part or Not Taking Part Affect My Health?**

Can I Withdraw from the Research and What Will Happen If I Withdraw?

Yes, you can withdraw from the study at any time. You do not have to give a reason. No-one will attempt to persuade you to continue.

Are There Any Expenses and Payments Which I Will Get?

Unfortunately no expenses or payments will be given for agreeing to participate in the study.

Will My Taking Part or Not Taking Part Affect My Health?

The study may rarely reveal information about you that could be relevant to your present or future health. If so, a doctor will give this information to you in confidence. They will also give you a letter detailing this information. You can give this letter to your usual medical doctor but only if you choose to.

If you decline to participate in this study, or withdraw from it during the testing, this will not prejudice you in any way..

Whom Do I Contact If I Have Any Questions?

You can contact the Chief Investigator:

Dr Iain Parsons,

Room C3/8, London District, Horse Guards. 0207 4142490

iain.parsons@kcl.ac.uk

Whom Do I Contact If I Have a Complaint?

Complaints can be directed to the Independent Medical Officer, Dr Will Wall. He is an Army doctor not involved in the study.

William.wall529@mod.gov.uk

02074142534

If you suffer any harm as a direct result of taking part in this study, you can apply for compensation under the MoD's 'No-Fault Compensation Scheme'.

What Will Happen to Any Samples I Give?

Processed blood samples will be frozen and may be retained for up to 2 years (whilst collecting the samples from other participants) before being analysed. Unused samples will be disposed of in the normal way hospitals do this. All samples will be anonymous and not identifiable to you.

Will My Records Be Kept Confidential?

Any information obtained during this trial will remain anonymous. Rarely a situation arises where we may wish to publish anonymous material that may be identifiable to you. If such a situation arises your permission will be sought in writing before anything is published. You should not feel obliged to give your consent; it is entirely voluntary. Other material, which cannot be identified with you, will be published or presented at meetings with the aim of benefiting others. You have a right to obtain copies of all records about you as well as all the papers and reports. All information about you is protected by rules that govern how we handle your data. All records will be kept securely.

Who is Organising and Funding the Research ?

This study is being organised by Dr Iain Parsons as part of a PhD (a higher degree) which is being performed at King's College London. It has been funded by the General Officer Commanding London District and the Commander, Home Command.

Who Has Reviewed the Study ?

This study has been reviewed and given favourable opinion by the Ministry of Defence Research Ethics Committee (MoDREC).

Further Information and Contact Details

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Compliance with the Declaration of Helsinki

This study complies, and at all times will comply, with the Declaration of Helsinki ¹ as adopted at the 64th WMA General Assembly at Fortaleza, Brazil in October 2013.

¹ World Medical Association Declaration of Helsinki [revised October 2013]. Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects. 64th WMA General Assembly, Fortaleza (Brazil).