School of Medicine and Public Health
UNIVERSITY OF WISCONSIN–MADISON

Consent Document

The Effect of Capsaicin-Phenylephrine-Caffeine Formulation on Aborting Tilt Induced Syncope in Patients with a History of Vasovagal Syncope or Near Syncope

NCT Number: NCT04972123

Principal Investigator: Mohamed H Hamdan, MD, MBA

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Phase IIa

University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research

Study Title for Participants: CPC Tilt Table Test Study

Formal Study Title: The Effect of Capsaicin-Phenylephrine-Caffeine formulation on Aborting Tilt Induced Syncope in Patients with a History of Vasovagal Syncope or Near Syncope

Lead Researcher: Mohamed Hamdan, MD, 608-263-1532
Where Lead Researcher works: School of Medicine and Public Health, Department of Medicine/Cardiovascular Medicine.

Invitation

We invite you to take part in a research study about vasovagal syncope or fainting. You are being invited because you have a history of vasovagal syncope or near syncope.

This consent and authorization form will give you the information you need to decide if you want to be in the study. It explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

Why are researchers doing this study?

The purpose of this study is to see if giving a new medication called CPC aborts a fainting spell during a Tilt Table Test. The new medication is called CPC, because it contains Capsaicin, Phenylephrine and Caffeine. The results from our first study with CPC showed that the drug was safe. The US Food and Drug Administration (FDA) has not approved the CPC medication for use outside of research studies.

Fainting is defined as transient loss of consciousness. Vasovagal syncope (VVS) is the most common type of fainting. It generally occurs after standing for a long time, or exposure to emotional stress or with pain or with medical procedures. Along with loss of consciousness people experience sweating, warmth, nausea and paleness. After VVS, most people will feel tired. Overall, the CPC medication is being studied to see if it would be useful in helping people abort or prevent fainting spells. We will also be assessing its impact on fatigue after a fainting spell.

This study is being done at the University of Wisconsin-Madison. A total of about 143 people will participate in this study.

What will happen in this study?
There is only 1 study visit at UW Hospital or UW Health Arbor Gate Heart Clinic during which you will have a Tilt Table Test and be given either the CPC medication or a placebo, together called study medication. A placebo looks like the real CPC but does not have the 3 active medications. Which group you are in will be decided by chance, like flipping a coin. Neither you nor the study team doing the Tilt Table Test will know which group you are in.

If you are on a medication to treat your fainting, you may be asked to hold it for about 48 hours before the study tilt table test. You will restart your medication 8 hours after the Tilt Table Test.

Before the Tilt Table Test, you will be asked to not have anything to eat or drink for 4 hours before the test. We will ask you about your medical history and all medications that you take. If you are of childbearing potential a urine pregnancy test will be done before the Tilt Table Test. The test must be negative for you to participant.

The Tilt Table Test will be done the same as other Tilt Table Test you may have had in the past.

- You will lie on the table and straps will be put around you to keep you safe when the table is being moved.
- You will have sticky patches called electrodes placed on your chest to monitor your heart rate and rhythm.
- You will have blood pressure cuff put on your arm and fingers, so we can monitor your blood pressure during the test.
- The table will be tilted upright for 20 minutes.
- If you have not fainted after the 20 minutes, you will be given Nitroglycerin under your tongue and tilted upright for another 15 minutes.
- If you do not faint during that 15-minute period the test will end.
- At any time if you start to feel like you are about to faint, you will be given the study medication.
- If you faint at any time during the test, the table to be returned to the flat position.

The study medication is given under your tongue. You will be asked to hold it under your tongue for 1 minute before swallowing it. You will be given sips of water after you swallow it. The upright tilt will continue for up to 5 minutes after you have been given the study medication. If you do not have pre-fainting symptoms during the test, you will not be given the study medication.

After the completion of the tilt table test, you will be asked to fill out a symptom survey at 1, 4 and 8 hours. You will stay in the clinic until you complete the 1-hour survey. You will be given the 4 and 8-hour survey to take home to complete and mail back to the study team.

You should resume any medications that were held before the Tilt Table Test 8 hours after the test. We also encourage you not to take any over the counter medications during the 8-hour period.

The total duration of your participation in this research study including the 1-hour wait time after test termination is estimated to be around 2 hours. UW Health requires that people who have had a Tilt Table Test have a driver to take them home.

Protected health information (PHI) used in this study
Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Results of tests done as part of the study
- Things you tell the researchers about your health
- Information currently in your medical record. This information includes your medical history, medications, results of other testing related to your fainting. We will get this information from your health care providers such as UW Health.

How long will I be in this study?
You will be part of the study for 1 day. Your study participation is finished after you complete and return the 4 and 8-hour questionnaires.

How is being in this study different from my regular health care?
This study is not part of your health care. It will not replace any medication that you may be taking to control your fainting spells.

Do I have to be in the study? What if I say "yes" now and change my mind later?
No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time. Let the researchers know if you choose to leave the study. If you stop being in the research, already collected data may not be removed from the study database. You may be asked if the investigator can collect data from your routine medical care.

If you decide not to take part in the study, or leave the study later, your choice will not affect any treatment relationship you have with healthcare providers at UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No

matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your PHI does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher,

  Dr. Mohamed Hamdan
  Cardiovascular Medicine
  600 Highland Ave. MC 3248
  Madison, WI 53792

Will being in this study help me in any way?
Being in this study will not help you directly. Your participation may benefit people in the future by helping us learn more about the best way to prevent a vasovagal fainting event.

This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

What are the risks?
Risk Related to CPC: As with all medications, there are side effects or risks. The results from our first study with CPC showed that the drug was safe. There may be other risks and side effects that are not know at this time.

The common risks related to CPC include

- Rapid heartbeat or awareness of your heartbeats called palpitations
- Increase in blood pressure
- Oral discomfort
- Stomach discomfort
- Headache
- Trouble falling asleep or staying asleep or insomnia
- Anxiety or excitability

The rare risks related to taking CPC include:

- Aspiration or fluid entering the lungs following the sips of water if you were to faint

Risks Related to the Tilt Table Test: Tilt Table Testing is generally safe and complications are rare. The known risks of the test include:

- Low blood pressure
- Pauses between heart beats
- Nausea or vomiting after fainting
- Weakness that can last several hours
- Headache – if you are given nitroglycerin.

These symptoms usually improve when the table is placed flat.

There is a risk that your information could become known to someone not involved in this study.

Reproductive Risks:
The study drug may harm a fetus or breastfeeding baby. If you are pregnant or breastfeeding, you cannot take part in this study. If you are able to become pregnant, you must have a negative pregnancy test on the day of study tilt testing.

Will being in this study cost me anything?
There will be no cost to you for being in the study.

Will I be paid or receive anything for being in this study?
We will pay you $200 for completing this study. Payment will be made after we have received the surveys you completed at home.

What happens if I am injured or get sick because of this study?
If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact the study team for instructions or contact your regular health care provider.
- Call the Lead Researcher, Dr. Hamdan at 608-263-1532 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.

- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

How will researchers keep my research information confidential?
We have strict rules to protect your personal information and PHI. We will limit who has access to your name, address, phone number, and other information that can identify you. We will store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring this study. This includes access to your medical records so that study monitors, auditors, the Institutional Review Board and regulatory authorities can verify study procedures and/or data. These groups will maintain your confidentiality. By signing this consent form, you are authorizing this access to your records. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information collected during this study for other research or share with other researchers without additional consent or authorization from you.

Who at UW-Madison can use my information?

- Members of the research team
- Study Data Monitoring Committee
- Offices and committees responsible for the oversight of research
- Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study

Who outside the UW-Madison may receive my information?

- The U.S. Food and Drug Administration (FDA)
- US Bank for support of stipend payments

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will information from this study go in my medical record?
An UW Health medical record will be created for you if you do not already have one. Some of the information we collect for this study will go in your medical record. This includes the results of your tilt table test. Both you and your UW Health providers will be able to see these results. A copy of this form will be placed in your medical record.

Will I receive the results of research tests?
You will have access to the Tilt Table Test Report placed in your medical record as required by federal law. You can access the report via UW Health MyChart or by requesting it from the UW Health medical records department. We will briefly discuss the results of the test with you before you leave the clinic. If you have additional questions, about the test results or concerns about your health, contact your primary care provider. You (or your insurance company) will be responsible for costs related to any follow-up care.

What if I have questions?
If you have questions about this research, please contact the Lead Researcher, Dr. Hamdan, at 608-263-1532. If you have any questions about your rights as a research subject or have complaints about the research study or study team, call the confidential research compliance line at 1-833-652-2506. Staff will work with you to address concerns about research participation and assist in resolving problems.

Agreement to Participate in Research Study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

_____

Printed Name of Research Participant

_____

Signature of Research Participant Date

_____

Signature of Person Obtaining Consent and Authorization Date

****You will receive a copy of this form****