NCT05649228

Study Title: Thermosensitivity of a Topical Palmitated Formulation of Capsaicin

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# PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

**TITLE:** A Double-Blind, Randomized, Pilot Study to Investigate the Thermosensitivity of a Topical Palmitated Formulation of Capsaicin

**PROTOCOL NO.:** None
WCG IRB Protocol #20221387

**SPONSOR:** Chorda Pharma, Inc.

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**STUDY-RELATED PHONE NUMBER(S):** 540-293-6899
540-224-5170
540-981-7000 (24 hours)

## SUMMARY

This consent form contains important information to help you decide whether to take part in a research study. You should read and discuss all the information in this consent form with the research study doctor. A brief summary of the study is provided below.

- Being in this research study is voluntary; it is your choice.
- If you join this study, you can still stop at any time.
- Do not join this study unless all of your questions are answered.
- This is a pilot research study that compares the potential of a modified capsaicin cream to an active control or placebo cream to cause irritation when a small amount (about the size of a quarter) is applied to each of your forearms.
- You will be asked to indicate your sensations at various time points following the application of the creams. If either of the medications produces a burning, tingling, soothing, freezing, or itching sensation, you are to categorize the sensations along a scale from 0 to 10.
- Your participation is expected to last one hour over one study visit, followed by a brief telephone interview 24 hours after the study visit.

- It is not expected that you will personally benefit from this research.
- Your alternative is not to participate.
- The most likely risks to you are temporary burning sensation or discomfort.
- Being in the study will not cost anything.

**The study staff will explain this study in detail to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.**

## DETAILED RESEARCH CONSENT

**Please read this entire consent form carefully.**

### WHAT IS INFORMED CONSENT?

Informed consent is the process of learning the key facts about a research study before you decide whether or not to volunteer. Your agreement to volunteer should be based upon knowing what will take place in the research study and how it might affect you. Informed consent begins when the research staff explains the facts to you about the research study.

The research staff will assist you with the informed consent form that goes over these facts so you can decide whether or not you want to take part in the research study. These facts include details about the research study, tests or procedures you may receive, the benefits and risks that could result and your rights as a research volunteer.

You are being asked to take part in a research study that compares the potential for discomfort for two different capsaicin creams. This study is being conducted as both a scientific as well as a commercial project by Carilion Clinic and Chorda Pharma, Inc. an early-stage pharmaceutical company. Your data will be compiled anonymously (de-identified) and may be used anonymously for publication in a scientific paper.

Before you can decide whether to take part in the research, you should be told about the possible risks and benefits with this study. This process is known as informed consent. This consent form will give you information about this study and your rights as a research subject. Being in this study is voluntary.

Be aware that the role of the study doctor is different from the role of your personal doctor. Your personal doctor decides how to treat your specific problem in order to help you. The study doctor treats all subjects under a specific protocol to obtain general knowledge that may or may not benefit you. Be sure to ask your doctors questions to help you know more about these different roles.

## WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to compare the potential for discomfort for two different creams that contain capsaicin. There will be 50 subjects from one location taking part. There will be one research study visit. The length of time you can expect to be in this research is approximately 1.5 hours. You will also be asked to complete a brief telephone interview 24 hours after the study visit.

## WHAT WILL HAPPEN IN THIS RESEARCH STUDY?

This is a study of the effects of capsaicin, the ingredient that makes hot peppers hot. Capsaicin is currently used in topical ointments to provide temporary relief of minor aches and joint pain associated with arthritis, simple backache, strains, and sprains.

This is a pilot research study that compares the potential of two different capsaicin creams to cause irritation or burning sensation when a small amount (about the size of a quarter) is applied to each of your forearms. The amount of capsaicin used in the creams is the same as those found in over-the-counter capsaicin products. The test creams are experimental.

The study visit will take approximately 1.5 hours. Research visits will take place in the Carilion Dermatology Clinic. There are three different creams being studied. Two of the creams contain different forms of capsaicin, and one cream does not contain any capsaicin (that cream is called a placebo). You will have two of the three creams applied to your skin, one on each forearm. The two creams that you receive will be randomly assigned, and we will not know which creams you receive. You will be asked to indicate your sensations on each arm at various time points (0-60 minutes) following the application of the creams. If either of the creams produces a burning sensation, you are to categorize the sensations along a scale from 0 to 10. At the end of the 24-hour period, you will be asked to wash off the applied creams with soap and water. At an exit interview, you will be able to discuss any further sensations you may have experienced.

The creams given to you will be assigned on chance using a method called randomization. Randomization means that the two creams that are applied to your forearms will be assigned by chance, like drawing numbers from a hat. You may receive a placebo treatment, which mean it does not contain any capsaicin. You have a 2 in 3 chance of getting one of the capsaicin creams and a 2 in 3 chance of getting the placebo cream. Everyone will get one of the capsaicin creams. Neither you nor your doctor will know which creams you are receiving. This information is available in the event of an emergency.

## WHAT ARE THE RISKS OF BEING IN THIS RESEARCH STUDY?

You should not participate in this study if you have had an allergic reaction to chili peppers or if you have ever had an allergic reaction to capsaicin topical creams.

The main risk is discomfort from the application of these test articles. A burning sensation or heat sensation may occur anytime within 3 hours of applying the cream to the skin. This has been described as "soothing" to very hot. A reddening of the site of application may also occur. If the burning becomes too uncomfortable then the applied cream should be washed off with soap/water or milk. These risks are considered moderate and are common. They may last up to 3 hours following application of the study drug.

You will be instructed not to touch the application site as this can allow the cream to be spread to other locations and cause a temporary burning sensation. You should not touch your eyes, nose, or mouth after the medication has been applied. If the medication gets on other areas of skin, it can be washed off for relief.

Warm water or perspiration can increase the burning sensation caused by capsaicin. If the burning becomes too uncomfortable then the applied cream should be washed off with soap/water or milk.

The study may have additional risks that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

## WHAT ARE THE RISKS TO A PREGNANCY OR TO A NURSING CHILD?

Taking part in this research may hurt a pregnancy or fetus in the following ways:

The effects of this study on unborn babies are not known. You must notify the principal investigator if you become pregnant. Any effect on your treatment or the effect on the baby will be discussed. Women of childbearing age are asked to have a pregnancy test before enrolling in this study. If you are unwilling to do this, you are asked not to sign up for the study.

## WHAT ARE THE BENEFITS OF BEING IN THIS RESEARCH STUDY?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include development of a pain relief medication with minimal side effects.

**WILL I RECEIVE NEW INFORMATION ABOUT THIS RESEARCH STUDY OR ABOUT MY STUDY RESULTS?**

Sometimes new information comes out during a research study that may affect your health, welfare, or willingness to stay in a study. If that happens, the researchers will tell you about the new information. You may decide you no longer wish to participate.

**WHAT ABOUT CONFIDENTIALITY?**

The research records will be kept in a secure computer database system call REDCap. All research data will be coded with a unique number. Your name and medical record number will be linked to the code number on a master list of those who take part in the study. This master list will be kept separate from the research database and will be stored in a locked filing cabinet. This master list will only be used by the researchers or organizations that govern research quality and safety oversight. Your identity will not be used in any sort of published report.

You research data and personal information collected as part of the research will not be used or distributed for future research studies, even if your identifiers are removed.

**AUTHORIZATION TO USE YOUR HEALTH INFORMATION:**

There is a federal law that protects the privacy of health information. This law is known as HIPAA. HIPAA stands for the "Health Insurance Portability and Accountability Act." Because of this law, your health information cannot be looked at, collected or shared with others without your permission.

Signing this consent and authorization form means you allow the Principal Investigator for this study and members of the investigator's research team to create, get, use, store and share information that identifies you for the purposes of this research.

**This is the information about you that researchers will use:**

- Personal identifiers such as name, address, telephone number, or medical record number.
- Demographic information such as age, race, gender.
- Current and past medications or therapies.
- Other personal health information that will be obtained from other sources to use in the research, including past medical history.
- Information from surveys or questionnaires done for this study.

**The investigator and research team may share information about you with:**

- The Carilion Clinic Institutional Review Board (IRB), and the WCG IRB, research protection groups that provide ongoing review of the research project.
- Authorized employees of Carilion Clinic who need the information to perform their duties to provide treatment, to ensure the integrity of the research or to do accounting and billing.
- Laboratories and other individuals and organizations that analyze your health information in connection with this research.
- The Office of Human Research Protections (OHRP), Food and Drug Administration (FDA), or other government agencies that oversee research with humans.
- Committees that monitor research data and safety or other groups authorized to monitor the study.
- The following sponsor or funding agency for the research: Chorda Pharma, Inc.

Health information that could allow you to be identified is called protected health information or PHI. The investigator and research team will share only the PHI listed above with the individuals/agencies listed above. If the investigator needs to share other PHI or needs to share PHI to other individuals/agencies not listed above, then you will be asked for your permission in writing again.

Carilion Clinic and its affiliates are required under law to protect your PHI. However, the individuals or agencies who receive your PHI may not be required by the Federal privacy laws to protect it. They could share your PHI with others without your permission, if permitted by the laws governing them.

You will not be eligible to participate in this study if you do not sign this consent and authorization form. Refusing to sign will not affect the present or future care you receive at Carilion.

You have the right to stop sharing your PHI. To end your permission to share your PHI, you must do so in writing to the Principal Investigator at the address listed on the first page of this form. If you want the researchers to stop collecting your PHI for the research, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or any other benefits you are entitled to receive. PHI collected for the research study prior to you ending your permission will continue to be used for the purposes of the research study. Also, the FDA (if involved with your study) can look at your PHI related to the study even if you end your permission.

You may not be able to see your PHI in your medical record related to this study until the study is complete. If it is necessary for your care, your PHI will be provided to you or your physician.

Research information continues to be analyzed or monitored after the study is finished so it is difficult to say when use of your PHI will stop. There is not an expiration date for this authorization to use and disclose your PHI for this study.

## WILL IT COST ME MONEY TO TAKE PART IN THIS RESEARCH?

Taking part in this research will not cost you any money.

Taking part in this research may lead to added costs to you, such as transportation costs or time away from work.

## WILL I BE PAID FOR TAKING PART IN THIS RESEARCH?

For taking part in this research and to compensate you for the time and effort of participating, you may be compensated up to a total of $40. Your compensation will be broken down as follows:

- Payment will be provided following completion of the study visit.
- If you do not complete the study visit for any reason other than a side effect of the topical medications applied to your forearms, you will not be paid.

Payments made to you as compensation for your participation will be tracked by the research team. This information will be submitted to Carilion's financial department for central tracking. If you receive greater than $600 from Carilion in a calendar year, this is considered taxable compensation and will be reported to the Internal Revenue Service (IRS). You will be issued a 1099 tax form by Carilion if you meet this reporting threshold.

## WHAT IF I WANT TO STOP BEING IN THE STUDY BEFORE IT IS FINISHED?

Being in this research is voluntary. You may refuse to take part or you may withdraw at any time without penalty or loss of benefits to which you are otherwise entitled. Your decision not to take part or your decision to withdraw will not affect your ability to get care from your doctors or from Carilion.

*If you decide to leave this research, contact the research team so that the investigator can remove you from this research.*

## CAN I BE REMOVED FROM THIS RESEARCH WITHOUT MY APPROVAL?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment not allowed in this research
- The research is canceled by the FDA or the sponsor
- You are unable to take the research medication
- You are unable to keep your scheduled appointments

The reason for any exclusion will be explained to you.

## WHAT WILL HAPPEN IF I HAVE COMPLICATIONS OR IF I AM INJURED BY THIS RESEARCH STUDY?

If you have a medical problem that happens because you are in this study, you will be able to get treatment. If you need emergency care, call 911 or go to your nearest hospital or emergency room right away. It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

The treatment will be billed to you or your insurer at the usual charge. The study does not make any planned provisions for the payment of these costs. You will not routinely receive any other financial compensation, or payment for any wages you may lose due to your injury. However, you do not give up any legal rights to seek compensation for injury by signing this consent form.

Call the person in charge of this study as soon as you are able. They will need to know that you are hurt or ill.

## ARE RESEARCHERS BEING PAID TO DO THIS STUDY?

None of the investigators or research staff will receive money or other benefits from the company that makes the investigational product being tested in this study. However, money or other benefits are going to a research fund, foundation, educational institution, or other organization with which one or more of the research staff is associated.

Carilion Clinic has partial ownership and holds equity interests in Chorda Pharma, the company sponsoring the research. In addition, two voting Chorda Board members who are employees of Carilion have a governing stake in Chorda. As a result of these interests, Carilion Clinic could potentially benefit financially from the outcomes of this research.

**WHO ARE THE CONTACT PERSONS?**

If you encounter complications or have any questions, concerns or complaints about the study, you may call:

Zachary Holcomb M.D.
Carilion Clinic
1 Riverside Circle, Suite 300
Roanoke, VA 24016
540-293-6899
540-224-5170
540-981-7000 (24 hours)
zeholcomb@carilionclinic.org

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.

This research is being overseen by an Institutional Review Board ("IRB"), WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

**IRB SURVEY:**

The IRB committee is a group of people that reviews research to protect the rights of research subjects. One job of the IRB is to make sure the research is done in a way that is respectful to subjects. If you agree, the Carilion IRB may select you to receive a survey asking about your experiences while taking part in this research study. If your name and address are given to the Carilion IRB in order to mail the survey, the Carilion IRB will keep this information confidential. You do not have to put your name or other identifying information on the survey unless you choose to do so or request to be contacted regarding your experiences. You do not have to give permission to allow the Carilion IRB to send you this survey. Please check below whether you agree to allow the Carilion IRB to send you a survey:

_____ Yes, I agree to Carilion IRB sending me a survey about my experiences while taking part in research.

_____ No, I do not want Carilion IRB to send me such a survey.

**CONSENT SIGNATURES:**

**RESEARCH SUBJECT:** The research study described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered. I consent to take part in this research study. My consent is given willingly and voluntarily. I may withdraw my consent at any time. I will receive a signed copy of this consent form.

_____
Printed Name of Research Subject

_____ _____
Subject's Signature Date

**PERSON OBTAINING CONSENT:** I certify I was present for the informed consent discussion. The subject had an opportunity to ask questions about and appeared to understand the information presented. The subject agreed to take part voluntarily in the research and I obtained their signature.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date