Protocol Title: A Novel Cooling Device for Pain Management During Fingerstick Blood Draws

Principal Investigator: Dieter Manstein, MD, PhD

Site Principal Investigator: N/A

Description of Subject Population: Healthy Volunteers

NCT05329493

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study as a healthy volunteer. We are doing the research to evaluate a novel tissue-cooling device for pain management during fingersticks for blood collection. If you agree, you will have a screening visit to determine eligibility, application of device to finger of right hand, finger prick, and blood collection. You will be in the study for 31 days if you decide to stay for the whole study.

The main risks of participating in the study are pain, swelling, redness, skin irritation and bruising.

You will be paid $150 using a debit card-based method for taking part in this research study. You will find more information about the payment amount for each visit and a plan if you do not complete all study visits later in this form.

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Dieter Manstein, MD, PhD is the person in charge of this research study. You can call him/her at 617-726-4454 M-F 9-5. You can also call Neera Nathan, MD at 617-982-2056 on M-F 9am-5pm with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call MGH Manstein Lab at (617) 726-4454.

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

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.

Why is this research study being done?

We are doing this research study to evaluate a novel tissue-cooling device for pain management during needle sticks and /or surgical procedures. The study will use a device developed in conjunction with Sunrise Labs, an experienced medical device development firm (https://www.sunriselabs.com/). The tissue-cooling device is not approved by the United States Food and Drug Administration (FDA) and can only be used in research studies such as this.

Who will take part in this research?

We are asking you to take part in this research study as a healthy volunteer because we need to assess healthy fingers to understand how numb the fingers become during the use of this device. We also want to determine the amount of blood that can be drawn by a finger prick during the use of this device. Up to 20 people will take part in this study at Massachusetts General Hospital Clinical Unit for Research Trials & Outcomes in Skin. The study will be funded by discretionary lab funds and will not use industry funds or grant funds.

What will happen in this research study?

Screening Visit

Screening procedures will take about 20 minutes. During the screening visit, the investigator will discuss the nature of the study, its requirements and its restrictions and will ask you to sign the consent form. The following will be discussed to determine if you qualify for the study:

- Review of inclusion/exclusion criteria with you (you should be ≥ 18 and ≤ 60 years of age at the time of enrollment; your fifth finger should be is 13-23mm in diameter at the distal phalanges and you must be able to read and understand English).
- Ask you about your medical history, medications you take and demographics (questions such as age, race, and ethnicity)

After the screening, if you qualify and are interested in participating in the study, we will schedule visit 1. If you don't qualify, the study doctor will tell you why.

*Subjects who fulfill all inclusion and exclusion criteria may begin the Visit 1 procedures that same day.

Visit 1

Visit 1 is expected to last approximately 1 hour.

The following assessments will be performed during Visit 1:

- A sterile glove will be placed on one hand. The top of the fifth or third finger of the glove will be cut and rolled up to promote venostasis (slowing of blood flow).
- The percent oxygen and pulse rate of the finger with the sterile glove and an untreated finger on the opposite hand will be measured with an oximeter.
- A layer of glycerol will be applied to the finger with the sterile glove before the cooling device is applied. The novel finger cooling device will then be applied to this finger.
- The device will be applied as a ring and will put low pressure on your finger. No more than four minutes after the digit cooling device is applied, we will prick the tip of your finger.
- On your other hand, we will prick the tip of your untreated finger for a total of two finger pricks. The pricks will be done using a disposable single-use lancing device.
- Whatman 903 filter papers will be used to collect any blood produced from each finger prick. Images of each Whatman 903 filter paper will be taken post blood collection.
- You will be instructed how to report a pain score for each prick. A visual 10-point pain scale will be used.
- Post-procedure pictures will be taken of both hands.
- A thermal camera will be used to video record the chiller hand until post-procedure pictures have been taken. The thermal camera will detect and measure the infrared energy (heat energy) coming from your hand.
- Regular video recording from the same area with a digital camera will be done simultaneously.
- Aftercare instructions and stipend will be provided, as well as a parking voucher if needed.
- You will be asked to send two photos (1 and 4 weeks after visit 1) from the areas that the device has been applied to the study's MGH secure email. An optional visit can be requested by the investigator if he cannot evaluate the treated area by the photos or if he believes an in person visit is needed for better clinical assessment.

Mass General Brigham has an electronic system that lets your study doctors know if you are admitted to a Mass General Brigham Hospital, or if you visit a Mass General Brigham Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side affects you experience while you are taking part in the study.

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

No. The research study we are doing is an evaluation of a novel tissue-cooling device for pain management during needle sticks and blood draws**.** Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research using your samples will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

What are the risks and possible discomforts from being in this research study?

a. Complications of prick procedure

The complications of prick include pain, swelling, redness, and bruising.

b. Device complications/malfunctions

The device is designed to apply pressure to the two main feeder vessels to the digit. The pressure applied is controlled by the study physician who will monitor tissue blanching (paleness of the skin) based on their clinical experience to ensure an appropriate amount of pressure/occlusion/blockage. In addition to monitoring pressure through tissue blanching, this study will limit the amount of time the device can be applied to the digit to 10 minutes or less. This time limit will be sufficient to prevent tissue ischemia (insufficient supply of oxygen), especially with the tissue cooling that will also be applied.

The device is designed to circulate cooling fluid. There are temperature indicators on the inlet and outlet tubing to the finger chiller. Temperature indicators will be checked and confirmed to be at the correct operating temperature prior to applying the device to you and during the finger pricking procedure.

If there were a leak of cold fluid onto your skin, the temperature of the cooling fluid is not cold enough to cause significant damage. The propylene glycol portion of the cooling fluid in the system is a food-grade propylene glycol conforming to United States Pharmacopeia standards and is GRAS (generally regarded as safe). According to the safety data sheet, it is considered to have low toxicity and may cause mild skin irritation. If the system is found to be leaking cooling fluid during the study, study staff will immediately remove the device from you and wipe the leaked fluid from your skin. Study staff will clean the affected area in accordance with standard cleaning procedures for intact skin.

The circulating fluid is chilled and pumped by a commercially available liquid chiller. If the chiller fails to maintain the circulating fluid temperature or if the pump stops pumping fluid, the temperature of the finger cooling device may rise, the device may not provide sufficient analgesia to the tissue and you may feel pain. If the chiller fails to maintain the -2.5 temperature or the pump fails to circulate the fluid, the inlet and outlet temperature sensors near the clamp will rise, providing feedback to the clinician to stop the experiment. You will be instructed by study staff to immediately report any pain to the study physician performing the treatment. You have the right to stop the study at any time if you feel pain or otherwise wish to stop the study

c. Non-Medical
There is a potential risk of loss of privacy. We will protect your privacy by labeling samples, information, and data files only with a study subject number code, and keeping the key to the code in a password protected database.

What are the possible benefits from being in this research study?

There are no medical or health benefits to subjects for participating in the study.

What other treatments or procedures are available for your condition?

We are not treating a medical condition in this study.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will be paid $150 for completing visit 1. This means we will pay you $150 if you complete the study. We will also provide a parking voucher for MGH main campus for each visit upon request.

We may be using an approved, outside vendor (Advarra Research) to make these payments to you via a reloadable card-based system, called Advarra Payments. This secure system is similar to a gift card or credit card.

If you are paid by this system, you will be given an Advarra Payments Visa card (which is just like a debit card) when you enroll in the study. Once the card is activated, the study team will add a payment after each paid visit you complete. The payment should be available to you within one (1) business day. Research staff will not know where you spend the money. You may use the card anywhere Visa cards are accepted, such as at a grocery store. If your card is lost or stolen, please call (617) 726-4454.

We will need to collect your Social Security number in order to make these payments, and it will be shared securely with the company that runs the card-based system. Payments like this are considered taxable income.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

What will you have to pay for if you take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs."

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)

- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____
Study Doctor or Person Obtaining. Consent	Date	Time (optional)

Consent Form Version: May 12, 2023