



RESEARCH CONSENT FORM

Protocol Title: *Cooling to Help Injured Lungs Pilot (CHILL-pilot) Phase IIb RCT of Therapeutic Hypothermia in ARDS Patients Receiving Neuromuscular Blockade*

Study No. : HP-00078506

Principal Investigator: *Jeffrey D. Hasday, MD 410-328-8141*

We are asking you to join a research study because you have injured lungs and may require your physicians to treat you with medications that cause deep sedation and muscle paralysis. Treatment with paralytic drugs have been shown to improve survival in patients with the type of lung injury that you have, which is called Acute Respiratory Distress Syndrome (ARDS). Participation in this study is voluntary and you may ask questions at any time. The word “you” in this form refers to the sick adult who will be in the study. Your legally authorized representative (LAR) will be asked to read and sign this consent form to give permission for you to participate, if you are unable.

This form gives you important information. Please read it carefully and ask questions before you make your decision. Whether or not you take part in this study is up to you. If you decide to take part in this study, we will ask you to sign this form. Before you sign this form be sure that you understand what this study is about, including any possible risks to you.

PURPOSE OF STUDY

The reason we are doing this study is to see if decreasing your body temperature from 37°C (98.6°F) to 34°-35°C (93.2°-95°) for 48 hours helps decrease the severity of lung injury. We will measure oxygen levels in your blood, the time that you need to remain on a breathing machine and time spent in the intensive care unit, and monitor your blood levels of glucose, essential salts, and indicators of kidney and liver injury.

We are asking you to join this research study because you have moderate to severe ARDS, which can threaten your life. About 40% of patients with ARDS like yours die. ARDS causes fluid to fill your lungs and makes it hard for you to breathe and to get enough oxygen. Your doctors are using a breathing machine to help you breathe and get more oxygen. There is information from studies in test tubes and animals and small studies in humans to suggest that cooling by 2°C (4.5°F) might reduce lung injury. You are eligible to enroll in this study because you have moderate to severe ARDS, but you will not be assigned to begin treatment (cooling vs. no-cooling) unless your doctors decide to give you medications that cause deep sedation and paralyze your muscles, which are frequently used to help treat patients with ARDS like yours. We will ask as many as 96 patients with lung injury like yours to join this study with the goal of assigning 32 to begin treatment over a 2-year period.

You will have a 1-in-2 (50%) chance (like flipping a coin) of getting one of the following treatments:

1. Cooled to 34°-35°C (93.2°-95°F) for 48 hours using cooling blankets or other external cooling devices; or
2. Standard treatment, which may include warming to keep body temperature close to 37°C (98.6°F) and treatment of fever over 38°C (100.4°F) using medications and cooling blankets.



Cooling will last 48 hours or until your sedation and paralysis is ended by your physicians (whichever occurs first) and you will be slowly warmed by 0.3°C (0.5°F) per hour until you reach 36°C (96.8°F). After you are rewarmed you will receive standard care but we will continue to follow you to see when you no longer need to be on a ventilator, no longer need to be in the ICU, and no longer need to be in the hospital. Because you are receiving deep sedation and paralytic drugs, you will feel no discomfort from the cooling. The same type of cooling that we are studying for ARDS is standard of care in patients who survive cardiac arrest because it reduces brain injury. It is not yet known whether a similar cooling treatment will reduce lung injury in ARDS although work in the test tube and in animal models of ARDS suggest it will. In order to learn more about whether cooling will help patients like you we have to study it.

If you agree to be in this study, we will immediately place cooling blankets or cooling pads on you and cool until your body temperature reaches 34°-35°C (93.2°-95°F). We will then adjust the cooling blankets to keep your temperature between 34°-35°C (93.2°-95°F) for 48 hours. We will collect 10 cc of blood (about two teaspoons) when you first enter the study and at five other times over the next week. We will also collect clinical information from the bedside over the first 7 days and from the medical record at 28, 60, and 90 days, but you do not need to remain in the hospital that long if you can be discharged sooner. If you are no longer in the hospital, we may call you after 90 days to find out how you are doing.

PROCEDURES

We will use cooling blankets or cooling pads to keep your body temperature between 34° and 35°C (93.2°-95°F) for up to 48 hours while you are receiving deep sedation and paralytic medications in the ICU. Normal body temperature is 37°C (98.6°F).

- We will do blood tests to monitor you while you are being cooled and up to 5 days later. When we can, we will use the blood and blood test results that your doctor gets for your care. This will reduce the amount of blood we need to take for the study. We will take up to 2 teaspoons of your blood at six different times (12 teaspoons total).
- Storing and future use of blood samples: We will freeze some parts of your blood samples and store them for up to two years after completion of the entire study for future studies of lung injury or other lung or critical care diseases. We will give all samples secret study numbers and try very hard to protect your privacy. Only your hospital study team will know your secret study number identity, which will be kept here in a locked file. The stored blood samples will not contain your name or identifying information. They will not be used to make cell lines. Some of these samples may be released to other investigators, but they will have no way to identify you.
- We will record measurements from your breathing machine. We will also collect information from your medical record while you are in the hospital. This information includes things like blood pressure, heart rate, temperature, your medicines, and whether there is any evidence of infection or failure of your organs.
- We may call you and/or your healthcare provider after you leave the hospital to find out how you are doing. We may also call to find out how you are doing for up to 3 months after you entered the study to find out how you were doing at the 28 day and 60 day points.



- We will give you any new information that may affect your decision to join this study.
- The study doctor may remove you from the study if it is best for you.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to: undergo cooling while receiving sedation and paralytic agents for up to 48 hours, have blood drawn up to 5 times for a total of 60 cc or 10 teaspoons, let us know how you are doing 28 and 60 days after entering the study.

POTENTIAL RISKS/DISCOMFORTS:

1. Cooling by 2 to 3°C may slightly increase your risk of infection but we will monitor you for infections and treat with antibiotics as needed.
2. Cooling by 2 to 3°C is likely to cause mild changes in your fluid and chemical balance, but these will be monitored closely and corrected.
3. Cooling by 2 to 3°C is likely to cause mild to moderate increases in your blood sugar levels, but these will be closely monitored and insulin given if needed.
4. Cooling by 2 to 3°C may slightly reduce the ability of your blood to clot normally, but you will be closely monitored for bleeding and treated appropriately.
5. Loss of confidentiality.
6. The risk of 12 teaspoons of blood drawn over one week is in keeping with similar studies, but may rarely contribute to low blood count in patients who already have significant blood loss. Your blood counts will be followed as part of the clinical management of your illness.

You can tell the study doctor, Jeffrey D Hasday or Carl B. Shanholtz, at 410-328-8141, if you feel that you are experiencing any side effects or have any questions regarding potential risks.

POTENTIAL BENEFITS

You may or may not benefit. There is no guarantee that you will receive direct benefit through your participation in this study. The knowledge obtained from this study will help doctors learn whether cooling can help other patients with lung injury.

ALTERNATIVES TO PARTICIPATION

Taking part in this study is voluntary. If you decide not to be in this study your doctor will decide whether or not you should receive cooling as part of your care. The quality of your care will be the same whether you join the study or not. The nurses, doctors, and other clinicians will do their best to give you the care you need for your illness, whether you join or do not join the study.



COSTS TO PARTICIPANTS

It will not cost you anything to take part in this study. You will have the costs normally associated with your care. The addition of mild cooling to your current level of care will not add to the total cost of your care.

PAYMENT TO PARTICIPANTS

You will not be paid for participating in this study.

CONFIDENTIALITY AND ACCESS TO RECORDS

This study will involve confidential information about your illness, but we will protect your privacy by removing your name and other personal information. Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the research study team, IRB and other representatives of this organization, the study Data and Safety Monitor and the Food and Drug Administrator. Only your study team in your hospital will know who you are and be able to tell which information and stored blood are yours. We do not think storing your blood for future studies has any risks or benefits for you.

The data from the study will be published in medical journal and in the Clinicaltrials.gov database. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator, Jeffrey D Hasday, MD, or Carl B Shanholtz, MD at 410-328-8141.

There will be no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research.

If you decide to leave, the study doctor may ask you if you are willing to have some follow up care or tests. If you leave the study, we will store your blood samples without your name. We will do so, unless you specifically request that they be destroyed. We will continue to collect information from your medical record until you go home unless you specifically ask us not to.

We will give you any new information that may affect your decision to join or stay in this study.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS



The University of Maryland, Baltimore (UMB) is committed to providing participants in its research the rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

Participating in research may result in an injury, as explained above. If you suffer an injury directly related to your participation in this project, UMB and/or one of its affiliated institutions or health care groups will help you obtain medical treatment for the specific injury and provide referrals to other health care facilities, as appropriate. UMB and/or its affiliated institutions or health care groups will not provide you with financial compensation or reimbursement for the cost of care provided to treat a research-related injury or for other expenses arising from a research-related injury. The institution or group providing medical treatment will charge your insurance carrier, you, or any other party responsible for your treatment costs. If you incur uninsured medical costs, they are your responsibility. The study staff can give you more information about this if you have a study injury.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland School of Medicine
Human Research Protections Office
Lexington Bldg, Second Floor
620 W. Lexington Street
Baltimore, MD 21201
410-706-5037



Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

To continue in this study.

_____ I agree _____ I do not agree

To be contacted by our study group after leaving the hospital to talk about other studies to learn how patients with lung injuries are doing.

_____ I agree _____ I do not agree

Participant's Signature

Signature of Surrogate

Date: _____

Relationship: _____

Date: _____

Investigator or Designee Obtaining Consent
Signature

Date: _____

Witness*

Date: _____

