eConsent Prochlorperazine versus Placebo for the Prophylaxis of Acute Mountain Sickness

Please complete the survey below.Thank you!

COMIRB Study ID: 23-0958

Form Version: 5 May 2024

Principal Investigator: Martin Musi, MD

Study Sponsor: International Society of Travel Medicine

Study Title: Prochlorperazine Maleate (Compazine) versus Placebo for the Prophylaxis of Acute Mountain Sickness

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

CONSENT AND AUTHORIZATION FORM

Why is this study being done?

This study plans to learn more about how we can prevent altitude illness, specifically a form called acute mountain sickness. Acute mountain sickness symptoms can include: headache nausea and vomiting, dizziness and fatigue.

You are being asked to be in this research study because it is important to find a better way to help prevent acute mountain sickness and because you would like to hike to and spend the night on the summit of Mount Blue Sky. Many people get altitude illness traveling to altitude, which can make people feel very sick.

Other people in this study

Up to 100 people from your area will participate in the study.

Up to 100 people around the country will be in the study.

What happens if I join this study?

This study is looking at if prochlorperazine (more commonly known as Compazine) can help prevent acute mountain sickness. Compazine is commonly used for migraine headaches and to treat nausea and vomiting. Participants will be randomized to either receive Compazine or an inactive pill called a placebo.
If you join the study, you will meet in Golden, Colorado where you will receive either the study drug or an inactive drug and receive breakfast. You will receive a basic physical exam (including leaving all clothing on) which involves a provider listening to your heart and lungs and taking vital signs including heart rate and blood pressure, and basic medical history. You will then be driven to Summit Lake near Mount Blue Sky where you will receive lunch, walk around and receive your second dose of the study drug or placebo You will then be taken on a guided hike to the summit of Mount Blue Sky where you will receive dinner, receive the third and last dose of the study drug or placebo, complete a survey called a Lake Louise Questionnaire (which helps determine if you have acute mountain sickness) and sleep overnight. In the morning you will receive breakfast, fill out another Lake Louise Questionnaire and then be driven back to the initial meeting point.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include altitude illness which can involve headache, dizziness, nausea, vomiting and fatigue.

Other possible risks include sunburn, dehydration, minor injuries that can happen while hiking.

Side effects of Compazine are uncommon but can include feelings of restlessness or agitation. Severe allergic reactions are very uncommon but can occur.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

You will be assigned to a study treatment by chance, and the study treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about how to prevent acute mountain sickness. Having a better way to help prevent acute mountain sickness would be very beneficial to all travelers to altitude which includes people traveling for fun and recreation, native populations, workers, rescuers and military personnel.

This study is not designed to treat any illness or to improve your health.

Who is paying for this study?

This research is being sponsored by the International Society of Travel Medicine.

Will I be paid for being in the study?

You will not be paid to be in the study. You will receive free access to the summit, free food and transportation.

Will I have to pay for anything?

You will not be charged for the study drug any of the study procedures or office visits for the study.

If you need more information about these costs, please discuss this with your study team.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

During the study, you will be closely monitored by Emergency Physicians at all times. In the event of an illness or injury resulting from your participation in this study, Emergency Physicians will immediately provide appropriate medical care. If needed, you will be evacuated to a hospital setting where you will be billed for care you may receive there.

Who do I call if I have questions?

The researcher carrying out this study is Elan Small. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Elan Small at 720-848-6777. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Elan Small with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on http://www.Clinical Trials.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.

What happens to data collected in the study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

• The data collected by investigators for this research no longer belong to you.
• Both the investigators and any sponsor of this research may study your data
• If data are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
• Any product or idea created by the researchers working on this study will not belong to you.
• There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:
• University of Colorado Denver | Anschutz Medical Campus

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Elan Small
12401 East 17th Avenue
7th Floor
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:
• Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
• The Institutional Review Board that is responsible for overseeing this research
• The study doctor and the rest of the study team.
Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make all or some of the following health information about you collected in this study available to: Belmar Pharmacy

Information about you that will be seen, collected, used and disclosed in this study:
• Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study.

I understand and authorize the access, use and disclosure of my information as stated in this form.

I know that being in this study is voluntary.

I choose to be in this study.

I will get a signed and dated copy of this consent form.

I agree to participate in this research and to provide my electronic signature.

◯ Yes
◯ No

Print name

_____

Digital signature (with mouse or finger)

_____

USE THE FOLLOWING ONLY IF APPLICABLE

Select one:

◯ Legally Authorized Representative
◯ Proxy Decision Maker

Print name

_____

Digital signature (with mouse or finger)

_____

Date completed

_____