Correlation and Comparison of the HepQuant® Disease Severity Index (DSI) With Hepatic Venous Pressure Gradient (HVPG)

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Study Title: Correlation and comparison of the HepQuant® Disease Severity Index (DSI) with Hepatic Venous Pressure Gradient (HVPG

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.

Why is this study being done?

This study plans to learn more about a new test to look at liver function, the HQ-Shunt. In this study, the HQ-SHUNT test will be compared to the Hepatic Venous Pressure Gradient (HVPG) test, and evaluated for safety, ease of administration, and comparative discomforts. HQ-SHUNT testing is considered experimental and is not yet FDA approved..

You are being asked to be in this research study because you have been scheduled to receive Hepatic Venous Pressure Gradient (HVPG) testing.

Other people in this study

Up to 110 people from your area will participate in the study.

What happens if I join this study?

If you join the study, you will be asked to come to the University of Colorado Hospital (UCH) Clinical Translational Research Center (CTRC) outpatient clinic for a screening visit and a study visit.

You will first complete the screening visit. At this visit, you will have a physical exam, review medical history and have a blood draw to see if you meet the other criteria for the study. If you meet the study criteria, then you will be entered into the study and will complete the study visit. The screening visit will take about an hour.

If you have already had the HVPG testing, you will have the option to continue with the study visit on the same day as your screening visit, or you can schedule your study visit for another day. The HQ-Shunt testing will be completed at the study visit. We will ask you to complete the study visit within 60 days of your HVPG testing. The study visit will last about 2 hours. You may schedule this study visit on a day that is convenient for you, but it must be within 60 days of your HVPG testing. You must fast (no food or drink except water) overnight before the morning of your study visit. If you are currently

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taking a beta blocker or an ACE inhibitor you be asked to delay taking your usual dose the morning of your study visit, until after the testing is complete.

Your study visit will include:

1. Placement of an intravenous catheter (IV): At the start of testing an IV will be placed in your arm. The IV will be used for administering HQ-SHUNT testing compounds and removing blood samples. The IV will stay in place for approximately 2 hours.2. Administration of HQ-SHUNT testing compounds: The testing compounds are forms of cholate. Cholate is naturally produced by your liver to help absorb food and small amounts are normally present in your blood . You will be given one form of cholate mixed in juice for you to drink (about 1/2 cup). At the same time another form of cholate will be given through the IV in your arm.

3. HQ-SHUNT testing blood draws: blood will be removed and analyzed to see how well your liver absorbs the two forms of cholate you were given. This will tell us how well your liver is working. Blood (1 teaspoon) will be drawn before you receive the HQ-SHUNT testing compounds. Then blood (1 teaspoon) will again be drawn 5 minutes after you receive the HQ-SHUNT testing compounds. Blood (1 teaspoon) will be drawn 4 more times, at 20 minutes, 45 minutes, 60 minutes, and 90 minutes, after you receive the HQ-SHUNT testing compounds. The total amount of blood drawn for HQ-SHUNT testing will be about 6 teaspoons at the study visit.

4. After completing the HQ-SHUNT testing, you will be asked to complete two surveys regarding your experience with the HVPG testing and the HQ-SHUNT testing.

If you are a woman who is able to become pregnant, you will have a urine pregnancy test at this visit. If pregnant you will not be allowed to continue in the study.

What are the possible discomforts or risks?

Risks of Having Blood Taken Screening Visit: We will get blood by putting a needle into one of your veins and letting the blood flow into a glass tube. You may feel some pain when the needle goes into your vein. A day or two later, you may have a small bruise where the needle went under the skin.

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Risks of having an IV Inserted in Your Vein: In this study we will insert a needle, connected to a plastic tube, into a vein in your arm. We will use the tube to take blood samples or give you fluids. You will feel some pain when we first insert the tube into your vein. You may have some redness, swelling, or bruising where the tube goes under your skin. In some cases, this type of tube can cause an infection where it goes under the skin. In rare cases, it can cause a blood clot in the vein. You will have this tube inserted for about 2 hours. The total amount of blood drawn will be 6 teaspoons.

Risks from test compounds: The two cholate forms used in this study are labeled with stable non-radioactive isotopes. Stable isotopes are naturally occurring heavy atoms that are everywhere and in everything, including our bodies. Stable isotopes do not decay like radioactive isotopes and do not produce any radioactivity so they are safe to ingest. The cholate forms used in this study have been enriched in these stable heavy atoms so the cholate forms can be measured in blood. These cholate forms have been registered with the FDA since 2002, and their use in humans has been monitored since that time. To date, the cholate forms used in this study have not been associated with any complaints or side effects. However, they are still considered experimental and there may be unknown risks.

Risks from Albumin: The cholate form that is given intravenously is bound to albumin, a protein which is a normal part of your blood. In rare cases, hypersensitivity reactions such as a rash, nausea and fever to albumin have occurred.

Risks from delaying your usual dose of beta blocker or ACE inhibitor: Delaying these medications could cause a mild increase in your blood pressure that morning, but the risks from this would be very low, similar to that of patients who miss doses of blood pressure medicine in everyday life.

Risks from Pregnancy: Researchers do not know if the oral or intravenous cholate is harmful to a fetus. Because of this, we will not enroll participants into this study who are or are planning to become pregnant. We recommend using a reliable form of birth control throughout the study. Hormonal birth control pills, intrauterine device (IUD), DepoProvera, Norplant, barrier methods (condom or diaphragm) plus a spermicidal agent, surgical sterilization, and complete abstinence are examples of reliable methods of birth control. Urine pregnancy tests will be done at the beginning of each visit to ensure you are not pregnant.

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 cannot be guaranteed.

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 the HQ-Shunt test.

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This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Who is paying for this study?

This research is being paid for by a grant from the state of Colorado from the Office of Economic Development and International Trade to Dr. Everson..

The new test to look at liver function, HQ Shunt test, was developed by Dr. Gregory T. Everson, at the University of Colorado Denver, and is licensed by HQ LLC. Dr. Gregory T. Everson is not only the inventor of the test but also founder, manager and equity member of HQ LLC. This means that Dr. Gregory T. Everson and the University of Colorado have a financial interest in the success of this study. Dr. Gregory T. Everson is a co-investigator in this study.

Will I be paid for being in the study?

You will be paid $*120.00* for completing all of the study visits. If you leave the study early, or if we have to take you out of the study, you will not be paid.

It is important to know that a payment for participation in a study is taxable income.

Will I have to pay for anything?

It will not cost you anything to be in the study.

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 choose to stop, you will be asked to write a brief voluntary note explaining your reason, but you do not have to write anything if you do not want to. If you choose to stop, you may request that any of your blood samples be destroyed and not used for the study. If you refuse to take part or decide to stop later, you will not lose any benefits or rights to which you are entitled. In this case your samples will be destroyed and not utilized in the study.

Can I be removed from this study?

You may be taken out of this study if the study doctor thinks it is not safe for you to be in the study. You can be taken out of the study even if you do not want to leave the study.

If you are taken out of this study, you will not lose any of the benefits that you would normally get outside of the study. Being taken out of the study will not affect your employment status or your reputation. Being taken out of the study will not change your

ability to get government assistance. If you are taken out of the study, the only benefits you will lose are the ones you are getting as part of this study.

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

If you have an injury while you are in this study, you should call Amanda Wieland, M.D. immediately. Her phone number is 720-848-2245. If you are hurt by this research, we will give you medical care. Medical treatment will be provided at no cost to you or your insurance company for a research-related injury. The sponsor and the investigator will determine if your injury or illness is research-related. The term "research-related injury" means physical injury caused by drugs or procedures required by the study which are different from the medical treatment you would have received if you had not participated in the trial.

Who do I call if I have questions?

The person in charge of this study is Amanda Wieland, M.D. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Amanda Wieland, M.D. at 720-848-2245. 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 Amanda Wieland, M.D. with questions. You can also call the responsible Institutional Review Board (COMIRB) at 303-724-1055.

You can also talk to a Research Subject Advocate at the University of Colorado Hospital (UCH) Clinical Translation Research Center (CTRC). The phone number there is 720-848-6662.

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.

Who will see my research information?

The University of Colorado Denver and the University of Colorado Hospital 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
- University of Colorado Hospital

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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 of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It 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 Primary Investigator, 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.

Amanda Wieland M.D.
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Anschutz Outpatient Pavilion
1635 Aurora Court
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.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and his/her team of researchers.
- *HQ LLC,* who is the company paying for this research study.
- Officials at the University of Colorado Hospital (UCH) Clinical Translational Research Center (CTRC) 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.

Information about you that will be seen, collected, used and disclosed in this study:

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- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of my previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records

What happens to Data and Blood Samples that are collected in this study?

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

- The data or blood samples are given by you to the investigators for this research and so no longer belong to you.
- Both the investigators and any sponsor of this research may study your data or blood samples collected from you.
- If data or blood samples are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or 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.

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.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Investigator: _____ Date: _____
Investigator must sign within 30 days

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Witness:_____ Date_____

Print Name: _____

Witness of Signature ☐

Witness of consent process ☐