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Study Title: *Per-Oral Pancreatoscopy-guided Lithotripsy vs. Extracorporeal Shock-Wave Lithotripsy For Treating Symptomatic Main Pancreatic Duct Stones in Chronic Pancreatitis*

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 what method of removing pancreatic stones is best in patients with chronic pancreatitis. We hope to compare two treatments that are both currently used to see which one is better. The device being used in this study is investigational, which means it has not is not approved by the FDA for this use.

You are being asked to be in this research study because you have chronic pancreatitis and you have stones in the pancreas that are hard to remove.

Other people in this study

Up to 50 people from your area will participate in the study. Up to 150 people around the country will be in the study.

What happens if I join this study?

If you join the study, you will be randomly chosen for one of the two main treatments we use to remove stones in patients with your condition. This study will have 2 different groups of research subjects like you. The two treatments are per oral pancreatoscopy-guided lithotripsy (PPL) and extracorporeal shock-wave lithotripsy (ESWL).

Per oral pancreatoscopy-guided lithotripsy (PPL) involves using an endoscope (flexible tube with a camera attached to the end) to get into the pancreatic duct (the drainage system of the pancreas). Once this access is achieved, a very small scope (pancreatoscope) is then placed directly into the pancreatic duct. This allows for direct viewing of stones in the pancreatic duct, which can then be broken up using either a laser or a shock wave.

Extracorporeal shock-wave lithotripsy (ESWL) involves the using a machine to shoot shock-waves from outside the body specifically into the pancreas. These shock-waves can eventually break up the stones inside the pancreas, which can help the stones eventually leave the pancreas.

The lithotripter device is routinely used clinically to perform this procedure, however the part of the machine that is used to destroy the pancreas stones is not approved by the FDA for this use.

To decide which group you will be in, we will use a method of chance. You will be assigned to a study treatment by chance, and the study treatment you receive may prove to be less effective or have more side effects than the other study treatment(s) or other available treatments. This method is like flipping a coin or rolling dice. Each group will get slightly different care. You would have received one of these treatments regardless of participating in this study or not. If the treatment you are assigned to does not work in clearing all the pancreatic stones, you may also undergo the other treatment. You will be asked to complete questionnaires about your medical history and lifestyle habits, your quality of life, pain levels and opiate use before receiving the treatment. You will then complete the questionnaires again (follow-up questionnaires), 1, 3, 6, 12, 18 and 24 months after finishing treatment.

You will receive these follow-up questionnaires via the email address you provided to us. If you do not respond within 7 days of receiving the questionnaire, a study coordinator may contact you by phone to kindly remind you to complete it or to assist you in answering the questionnaire.

Per standard of care, you may also have blood draws, stool tests, and undergo imaging tests. We may collect these results if they were performed in the last 12 months prior to you starting your treatment as well as during your study participation (which will be from this consent form signature to 2 years after completing your treatment). Abdominal X-rays may be performed to confirm your post-treatment status after one or more procedures per standard of care.

What are the possible discomforts or risks?

The most common risks of undergoing per oral pancreatoscopy-guided lithotripsy includes pancreatitis (inflammation of the pancreas), bleeding, cholangitis (inflammation of the bile duct) and cholecystitis (inflammation of the gallbladder). Less common risks include duodenoscope-related infection (infection due to contamination of the medical instrument used during the procedure) and perforation, or a small hole made in the wall or an organ.

The most common risk of undergoing extracorporeal shock-wave lithotripsy (ESWL) is post-ESWL pancreatitis (inflammation of the pancreas). Some significant and substantial risks of this particular operation or procedure include (but are not limited to): sepsis, infection, bleeding, injury to pancreas, steinstrasse (when stone fragments block the pancreatic duct), bruising of skin tissue along the path of the shock wave, tenderness occurring at the skin tissue that is in contact with the shockwave, incomplete fragmentation of the stone requiring alternative treatment, stone migration, inability to access stones(s), no stones, need for further procedures, loss of pancreas and/or death. Rare risks can include a perforation (small hole made in the wall or an organ), a pancreatic duct leak (when pancreatic fluid leaks from the pancreatic duct) and cardiac arrhythmias

(irregular heartbeat). Machine malfunction may occur necessitating rescheduling. In addition, the stones might not get removed completely.

After either of the procedures, you might experience increased abdominal pain, which could require extended monitoring. This pain could stem from the manipulation of the pancreatic duct, movement of stones and/or fragments, or be a result of other adverse events.

These risks can be serious and possibly fatal.

Blood draws may cause fainting and some pain and/or bruising at the site on your arm where the blood was taken. In rare occasions, an infection may occur.

Discomforts you may experience while in this study include psychological harm from the questionnaires as they do ask about your personal life.

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.

If you are pregnant, the particular treatment or procedures involved in the study may involve risks to the embryo or fetus which are currently unclear. **Please tell your study doctor if you could be pregnant.**

There may also be unknown risks not listed that you may experience during this study.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about which method to remove stones is better. This will help researchers also understand how stone removal affects quality of life and pain.

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.

Are there alternative treatments?

There may be other ways of treating your chronic pancreatitis. You may choose to get not treatment at all or you could consider surgical removal of part of your pancreas.

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

This research is being funded by Boston Scientific and a private grant. However, your procedures are being paid for by your insurance, as they are part of standard of care.

Raj Shah (the principal investigator) has a financial interest in Boston Scientific Corporation, which is the company paying for the study. Please feel free to ask any additional questions you may have about these matters.

Will I be paid for being in the study?

You will receive $50 after your treatment procedures are completed.

You will receive $25 for each of the follow up questionnaires you complete (at 1, 3, 6, 12, 18 and 24 months).

If you complete all study activities, the total payment for your participation in this study will be $200. You will only be paid for the activities you complete.

You will receive a separate check for each of the payments. It is important to know that payment for participation in a study is taxable income.

Will I have to pay for anything?

You will need to pay for the cost associated with this study treatment program. It will be charged to you or your insurance carrier. The treatments being evaluated in this study are all part of standard clinical care and are covered by insurance. You will not incur any additional costs for participating 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 refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

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. Also, the sponsor may stop the study at any time.

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

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Raj Shah. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Fernanda Pessorrusso at 303-724-9228 or 720-236-4541 (24 hours). 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 Fernanda Pessorrusso 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.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus and its affiliated hospital(s) 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
- University of Colorado Hospital

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.

Raj Shah, MD
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Campus Box B158
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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;
- People at the Colorado Multiple Institutional Review Board (COMIRB), the institutional review board that is responsible for overseeing this research;
- Boston Scientific Corporation;
- 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.

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;
- Portions of your 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 that are collected in this study?

Scientists at the University and the hospitals 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 given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study your data collected from you.
- If data 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 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.

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)

Signature:_____

Use the following only if applicable:

A signature of a witness is required for consent of non-reading subjects and consent using a short form.

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Witness Signature:_____ Date: _____

Print Name:_____

Witness of Signature Witness of consent process