INFORMATION SHEET

TITLE:

Sonothrombolysis in Patients with an ST-segment Elevation Myocardial Infarction

A prospective single-arm study

INVESTIGATORS:

H. Becher, MD	U of A, Division of Cardiology	780-407-3731
J. Choy, MD	U of A, Division of Cardiology	780-407-3581
K. Bainey, MD	U of A, Division of Cardiology	780-407-2176

BACKGROUND

You were asked to take part in this research study because you were having a heart attack (myocardial infarction). The myocardial infarction happened because one of the arteries on your heart muscle had been blocked by a blood clot. The current treatment is coronary angiography, to re-open the blocked artery with a balloon catheter and keep it open with a stent.

The research procedure was explained to you prior to the initial treatment and you have signed a shorter version of this form. Before you make a decision to continue with this study one of the researchers will go over this form with you. You are encouraged to ask questions if you feel anything needs to be made clearer. You will be given a copy of this form for your records.

This research study is looking to see if the way we re-open the blocked artery can be improved using ultrasound and ultrasound contrast agent. Ultrasound uses sound waves to develop images of the inside of the body. Ultrasound contrast agents are medications injected into a vein during ultrasound to help make pictures of the inside of the body more clear. Ultrasound contrast agents consist of microbubbles which make small movements in the blood when exposed to ultrasound. There is evidence that these tiny movements can be used to dissolve blood clots. A previous study has shown that the coronary arteries blocked by blood clots were opened faster when ultrasound imaging of the heart with contrast agent is combined with the standard treatment for heart attack. That study used an ultrasound scanner which was different from the ultrasound scanner used here in Edmonton at the Heart Institute. This study is looking at whether we can achieve similar effects with our ultrasound equipment.

PURPOSE

You have had a heart attack. Standard treatment at this hospital is coronary angiography, to re-open the blocked artery with a balloon catheter and keep it open with a stent. The aim of this research study is to see whether ultrasound applied to the patient's chest and use of ultrasound contrast agent can open the blocked arteries. This treatment was given in addition to the standard treatment and while you were being prepared for the standard treatment. After the standard clinical treatment (coronary angiography), additional ultrasound applications were performed. The additional ultrasound was intended to dissolve smaller blood clots in smaller

arteries and to assess whether the ultrasound treatment was successful in opening the arteries. A previous study has shown this treatment resulted in opening of the blocked arteries. However, we would like to find out whether similar results can be obtained with a newer ultrasound machine.

ABOUT THE STUDY TREATMENT

The study treatment includes ultrasound and contrast agent. We will use an ultrasound machine which is in clinical use for diagnostic imaging. The contrast agent, called Definity®, is also normally used in clinic to enhance the ultrasound images. However, in this study we are using both the ultrasound machine and contrast agent as part of the treatment for heart attack (instead of for diagnosis) and this is considered research. Health Canada has approved this study to test this treatment.

DESCRIPTION OF THE STUDY

While you were being prepared for angiography in the emergency room or cath lab, an ultrasound probe was placed on your chest by a physician and the ultrasound contrast agent Definity® was injected through a venous catheter which had already been inserted in the ambulance. The physician scanned your heart using the same technique which is the standard in clinical practice to assess the blood flow to and from the heart muscle. By alternating the power of the ultrasound the physician assessed the flow of the contrast agent in vessels of the heart muscle. While this takes usually a few minutes for diagnostic purposes, this was performed for 15-20 minutes during study. The ultrasound scanning was performed while the preparations for the coronary angiography took place. Thus, there was no delay in receiving the standard medical treatment.

This was followed by coronary angiography which is the standard of care in your case. The physicians checked whether the blocked coronary artery was already open and if not, attempts were made to open the artery with a balloon catheter and kept open with a stent. Then additional ultrasound imaging with contrast infusion was performed for another 10 minutes.

In addition to what described above, participation in this study will require two further diagnostic ultrasound examinations of the heart (echocardiograms), one prior to discharge from the hospital which is standard of care and another after 3 months. At these two time points, an echocardiogram with intravenous injection of the ultrasound contrast agent Definity® will be performed. Each ultrasound examination will take around 30 minutes and will allow us to assess the recovery from the heart attack.

The study will involve 15 patients. If this study shows benefit in opening of the arteries, a larger study will be arranged in order to collect the evidence required for using contrast ultrasound for treatment of myocardial infarction in clinical practice.

<u>If you decide not to take part in this project, this does not affect your treatment plan in any way. You will still receive all required tests and assessments for your care.</u>

POSSIBLE BENEFITS

There may be no direct benefit to those patients participating in this study. If this study shows benefit, it will allow us to proceed with further studies that can lead to more effective treatment of patients with myocardial infarction.

RISKS
During ultrasound scanning some discomfort may be experienced from the slight pressure applied to the probe on the chest.

The contrast agent Definity® has been widely used for diagnostic purposes. Small risks are involved with the injection. The undesirable effects reported with Definity® are, in general, non-serious, temporary and resolve spontaneously without residual effects. The following transient side effects have been observed in clinical trials: headache 2.35%, back pain 1.2%, flush 1.1%, nausea 1 %, chest pain 0.8%. Severe allergic reactions are very rare - around 1 in 10,000 applications.

Spasm of the heart arteries has been reported in a sonothrombolysis study that used higher ultrasound energies. Spasm of the heart arteries has not been reported in any study that has used ultrasound energies similar to what was used in this study.

In the unlikely event that any of the above reactions should occur, the department is fully equipped with all the necessary equipment, medication and experienced personnel needed to treat you appropriately.

COMPENSATION FOR INJURY
If you become ill or injured as a result of being in this study, you will receive necessary medical treatment, at no additional cost to you. By signing this consent form you are not releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

COSTS

You will not have to pay for the assessments that you receive in our clinic and your prescribed treatments will be covered by your current health plan. All visits to the clinic will be part of routine care.

CONFIDENTIALITY
During the study we will be collecting health data about you. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your name will be released outside of the study doctor's office or published by the researchers. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your health information is kept private.

The study doctor/study staff may need to look at your personal health records held at the study doctor's office, and/or kept by other health care providers that you may have seen in the past (i.e. your family doctor). Any personal health information that we get from these records will be only what is needed for the study.

During research studies it is important that the data we get is accurate. For this reason your health data, including your name, may be looked at by people from the University of Alberta clinical auditors, the Health Research Ethics Board, and/or Health Canada.

By signing the consent form you are giving permission for the study doctor/staff to collect, use and disclose information about you from your personal health records as described above. Study information is required to be kept for 25 years. If you leave the study, we will not collect new health information about you, but we will need to keep the data that we have already collected.

VOLUNTARY PARTICIPATION

You do not have to be in this study to receive care at this hospital. Further, even if you decided to be in the study, you are free to withdraw at any time, and your continuing medical care will not be affected in any way. If any knowledge gained from this or any other study becomes available which could influence your decision to continue in the study, you will be promptly informed.

CONTACT INFORMATION

If you have any questions or concerns, please contact the investigators listed below:
Dr Kevin Bainey at 780 407- 2176, Dr Harald Becher at 780 407-3731 and Dr Jonathan Choy at 780 407-3581

If you have any questions or concerns about your rights as a study participant, you may contact the Research Ethics Office at 780 492-2615. This office is independent of the study investigators.

CONSENT FORM

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Investigators

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Please answer the following questions:	**Yes**	**No**
Do you understand that you are being asked to participate in a study?	___	___
Have you read and received a copy of an attached information sheet?	___	___
Do you understand the benefits and risks in taking part?	___	___
Have you had an opportunity to ask questions and discuss this study?	___	___
Do you understand that you are free to withdraw at any time without having to give a reason and without affecting your future medical care?	___	___
Has the issue of confidentiality been explained to you, and do you understand who will have access to your medical records?	___	___
Do you want the investigator(s) to inform your family doctor that you are participating in this research study? If yes, give his/her name: _____	___	___

Who explained this study to you? _____

I agree to take part in this study.

Name and signature of the research participant Date

Signature of the person who obtained consent

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Name and signature of the person who obtained consent Date