

****FOR CCI USE ONLY****

Approved by the Beth Israel Deaconess Medical Center Committee on Clinical Investigations, New Procedures and New Forms of Therapy:

Administrator: _____ **Date:** _____

Protocol Number: _____ **Expiration**
Date: _____

INFORMED CONSENT

- Subject's name: _____
- Title of Research Protocol: **Ethanol Ablation in Hypertrophic Obstructive Cardiomyopathy**
- Principal Investigator's Name: Joseph Carrozza
- Co-Investigators: Roger Laham, Beverly Lorell, David Cohen, Donald Baim, Peter Zimetbaum, Mark Josephson, Joseph Kannam
- Protocol Number: W-00-0135-FB

D1. PURPOSE OF STUDY:

The purpose of this study is to use ethanol to induce a controlled heart attack (damage) to the septum (a part of your heart) which is causing an obstruction (blockage) to the flow of blood into your arteries and causing symptoms that are not controlled with medicine alone.

D2. SUBJECT SELECTION:

Your doctor has determined that you have a condition called hypertrophic obstructive cardiomyopathy which consists of enlargement of a portion of the heart (the septum) and an obstruction (blockage) to the flow of blood into your arteries. Your doctor has also determined that medications are not sufficient to relieve the obstruction (blockage) and control your symptoms. Traditionally, patients with your condition undergo open heart surgery with removal of the septum (myectomy) which may potentially remove that obstruction. Because, this involves open heart surgery and the procedure is very invasive, your doctor wants to have you considered for an experimental approach using ethanol (alcohol) to damage the septum and relieve the obstruction that way.

D3. PROCEDURE:

After determining eligibility for the procedure, including having symptoms that cannot be controlled with medicine, you will undergo pre-procedure evaluation including an ultrasound (a probe that emits ultrasound waves to have an image of your heart) of the heart, answering questions on a Questionnaire regarding your symptoms and how you feel, and undergoing a stress test (walk on a treadmill), as well as blood tests, you will undergo a cardiac catheterization (insert catheters from your groin all the way to your heart and inject a substance under Xray to have a picture of your arteries) to make sure that you do not have coronary artery disease and that you have a gradient (way to measure obstruction to the flow of blood). After baseline measurement of the state and pressures of your heart, the major artery (septal) that gives blood to your part of the heart that is causing the problem (septum) is located, and an appropriate sized balloon is used to close the septal. Ethanol is then infused slowly in the occluded septal using 2-3 ml depending on the size of the septal with heart monitoring.

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You will then be monitored for two days in the intensive care unit and will be kept in a stepdown unit until you recover from the controlled heart attack damaging the septum. Your medicine will be continued as per your cardiologist and physicians. Routine care is carried out for the septal myocardial infarction and a consultation is obtained from the electrophysiology service (pacemaker doctors) for the potential need of a permanent pacemaker (implanted battery to keep your heart beating regularly). You will undergo follow-up transthoracic echocardiography (ultrasound of your heart), blood tests, answering the questionnaire about your symptoms and how you feel. You will be followed up after discharge at day 7, 15, 30, 90, and 6 months. Echocardiography (ultrasound of the heart) is performed at day 90 and 6 months. Answering the questions on the questionnaire will be performed at days 15, 30, 90, and 6 months at which time a treadmill exercise test is performed.

D4. RISKS AND DISCOMFORTS:

- Complete heart block necessitating permanent pacemaker placement (disconnection of the upper and lower chambers of the heart) which may occur in up to one third of patients. The pacemaker is a battery to make your heart continue to beat regularly. In fact, you may already have a pacemaker since they were used in the past to treat patients with your condition.
- Ventricular arrhythmias (abnormal rhythm of the heart) associated with the controlled heart attack as well as late ventricular tachyarrhythmias (abnormal heart rhythm of the heart) which may be deadly (may occur in up to 1 in 10 patients). Treatment may include medicines and electric shock.
- Leak of ethanol into the left anterior descending artery (main artery of the heart) resulting in a larger heart attack which may increase your risk of dying.
- Death from ventricular arrhythmias (abnormal rhythm of the heart) or cardiac failure (failure of the heart to function with build up of fluid in your lungs) which may occur in up to 3-4% of patients
- Damage to the main artery of the heart from the instrumentation in the procedure necessitating further intervention (angioplasty/stenting to open the artery which may occur in less than 1% of patients
- Discomfort from the catheterization and the controlled heart attack including chest pain, groin pain
- Complications of cardiac catheterization: bleeding, infection, artery damage in the groin (less than 3%), stroke (damage to the brain) in less than 1%, emergency bypass surgery (less than 2%)
- Prolonged hospital stay for monitoring
- Arrhythmias (abnormal heart rhythm) from exercise testing (less than 5%) which would require electric shock
- This research study may involve exposure to radiation associated with the balloon location and ethanol infusion. The amount of radiation exposure you will receive from this procedure is equivalent to a uniform whole body exposure of 1.7 rem. This is equivalent to 34 % of the annual radiation exposure limit allowed for a radiation worker (such as the cardiologist performing your procedure). The risk from radiation exposure of this magnitude is considered to be comparable to other every day risks.

D5. BENEFITS:

It is not possible to predict whether you will benefit directly from this procedure.

You may benefit from the procedure by elimination or reduction of the obstruction and symptoms, removing the need for surgery

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D6. ALTERNATIVE PROCEDURES:

Alternative treatment include continued medical therapy with symptoms or surgical myectomy (open heart procedure to remove the septum surgically). The death rate from the surgical procedure that corrects the obstruction has been reported to be between 4.7% and 7.5% in surgical studies. Whatever your decision is, your care is independent of your participation in this study.

D7. COST/PAYMENT:

You will not be paid to participate in this study. Since this procedure is undertaken to provide alternative therapy, the procedure and all surrounding tests will be billed to your insurance as would any treatment provided to you. All the follow-up tests that are performed with the exception of the Questionnaire are routine tests that would be done if you had undergone the surgical procedure or continued on medical therapy. Therefore, they would be billed to your insurance and you would be responsible for any co-payments that may be necessary. The Questionnaires are provided free of charge since they are not part of your routine care.

D8. COMPENSATION FOR INJURY:

If, during the course of the study, any injury should occur to you, you must contact a member of the research team immediately. Beth Israel Deaconess Medical Center will provide medical treatment for any illness or physical injury directly resulting from research procedures. The cost of such treatment will be billed to your insurance as would any medical care provided to you.

D9. PARTICIPATION AND WITHDRAWAL:

Participation in this study is voluntary. You have the right to refuse to take part in this study. If you choose to participate, you have the right to withdraw at any time. Refusal to participate in the study will involve no penalty or loss of benefits to which you are entitled, and will not affect your present or future medical care at the Beth Israel Deaconess Medical Center. If a significant new finding develops during the study that may influence your willingness to participate, you will be informed as soon as possible. You may also be withdrawn from this study without your permission if, in the opinion of the investigators or your physician, further participation will be detrimental to your health.

D10. If you have any questions or experience problems you should contact Dr. Roger Laham at (617) 667-4138.

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D11. CONFIDENTIALITY:

Information derived from this study and from your medical record may be reviewed and photocopied by the Food and Drug Administration (FDA) and/or state and federal regulatory agencies and the Committee on Clinical Investigations of the Beth Israel Deaconess Medical Center with protection of confidentiality so far as permitted by applicable law. Information resulting from this study and from your medical record may be used for research purposes and may be published, however, you will not be identified by name in such publications.

Date submitted to Committee: _____

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CONSENT FORM FOR CLINICAL RESEARCH

I have read the previous page(s) of the consent form and the investigator has explained the details of the study. I understand that I am free to ask additional questions.

If I wish additional information regarding this research and my rights as a research subject, or if I believe I have been harmed by this study, I may contact the Chairman of the Medical Center's Committee on Clinical Investigations at (617) 667-4272

I am aware that this is a research project and that unforeseen side effects may occur.

I understand that the Beth Israel Deaconess Medical Center has no formal program for compensating patients for medical injuries arising from this research. Medical treatment will be provided for injuries at the usual charge to me or to my insurer unless payment is otherwise provided for in this consent form.

I understand that I may be contacted by the Beth Israel Deaconess Medical Center's Committee on Clinical Investigations during or after my participation in this study as part of its efforts to monitor the experience of subjects in clinical investigations.

I understand that participation in this study is voluntary and I may refuse to participate or may discontinue participation at any time without penalty, loss of benefits, or prejudice to the quality of care which I will receive.

I acknowledge that no guarantees have been made to me regarding the results of the treatment involved in this study, and I consent to participate in the study and have been given a copy of this form.

_____	_____	_____	_____
WITNESS	DATE	STUDY SUBJECT	DATE
_____			_____
PARENT OR LEGAL GUARDIAN			DATE
(If subject is a minor, or subject is unable to give consent)			

The subject has been given the opportunity to read this consent form and to ask questions before signing, and has been given a copy.

_____	_____	_____
PRINT INVESTIGATOR'S NAME	SIGNATURE OF INVESTIGATOR (or designee)	DATE
For any questions regarding the rights of a research subject, or information regarding treatment of research-related injuries, please contact Nan Clark, Manager, Research Administration, (617) 667-3743		

