

Consent for Coronary Artery Risk Factor Reduction Registry

Are you participating in any other research project?

Yes No

Experimental Subject Bill of Rights

Persons who participate in a medical experiment are entitled to certain rights. These rights include but are not limited to the subject's right to:

- Be informed of the nature and purpose of the experiment;
- Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
- Be given a description of the any attendant discomforts and risks reasonably to be expected;
- Be given a disclosure of any benefits to the subject reasonably to be expected, if applicable;
- Be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- Be informed of the avenues of medical treatment, if any available to the subject after the experiment if any complications should arise;
- Be given the opportunity to ask questions concerning the experiment or the procedures involved;
- Be instructed that consent to participate in the medical experiment may be with drawn at any time and the subject may discontinue participation without prejudice;
- Be given a copy of the signed and dated consent form;
- And be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

XI. Informed Consent

INFORMED CONSENT FOR CORONARY ARTERY RISK FACTOR REDUCTION REGISTRY

Name of Physician:

Address:

Name of Patient:

- I. Title of Project—A Registry to Evaluate Clinical Outcomes in Patients with Coronary Artery Disease Treated with Nutritional Supplements and EDTA with Magnesium to Reduce Risk Factors that Contribute to Arterial Plaque Production.

By my signature on this document, I am indicating that I am a patient of the above listed doctor, who is my chelating physician and that I desire to participate in a research project known as a Registry for Coronary Artery Disease Risk Factor Reduction involving treatment with EDTA (Ethylenediamine tetraacetic acid) chelation therapy and nutritional supplements. This program in my case will involve the use of this chelating agent and selected nutritional supplements to reduce my risk of developing further blockages to the blood vessels that supply oxygen and nutrients to my heart.

- II. Purpose of the Study

I understand that this project is sponsored by the American College for Advancement in Medicine (ACAM) and is conducted under the supervision of the ACAM Institutional Review Board (IRB) and the Great Lakes College of Clinical Medicine IRB to protect patient safety. The purpose of the Registry is to establish whether risk factor reduction by intravenous (IV) administration of EDTA with magnesium and the addition of certain nutritional supplements will reduce the future incidence of major cardiovascular events such as sudden death, heart attack, hospitalization and stroke in patients with existing coronary artery disease.

Patient enrollment in the Registry will continue for approximately two years after it begins in October, 1999 and will involve 2000 patients. EDTA chelation therapy is a treatment approved by the Food and Drug Administration for heavy metal toxicity, hypercalcemia and the control of heart rhythm problems associated with digitalis. Its usage is considered to be experimental by most physicians (including cardiologists and cardiovascular surgeons) for coronary artery disease risk factor reduction, although a minority of physicians have used it safely for this purpose since the 1950's. My treating physician believes that EDTA chelation therapy does reduce risk factors for vascular disease and that it might be helpful in my case. He or she also believes that certain nutritional supplements might be of significant benefit to reduce vascular disease risk factors. My physician is hopeful that this study might result in a broader acceptance of chelation therapy and nutritional supplements to reduce the risk of vascular disease.

- III. My risk factor reduction in this Registry will include the following:

- A. During my initial evaluation, a history and physical examination, various laboratory tests of my blood and urine, noninvasive vascular testing, and a symptom questionnaire will be done. Several tubes of blood will be drawn.

- B. Risk factor reduction will include a series of intravenous solutions (fluid flowing into my veins through a needle), which contain EDTA (a synthetic amino acid), magnesium, potassium, vitamin C, and other additives in either 250 ml or 500 ml of solution. I will receive a basic course of 30 treatments (or more if deemed necessary by my physician), each session lasting 1 1/2 to 3 hours, depending on the dose, at intervals of 1-3 times per week. I will also need to take oral vitamins and minerals daily.

If I am in group B, additional nutritional supplements will be prescribed by my physician based on specific risk factors identified by additional laboratory testing done during my initial evaluation. This part of the Registry will not be required if I am in Group A.

At the conclusion of the basic course of treatments with intravenous EDTA, additional maintenance treatments will be provided to me once a month and oral supplements will be continued.

I will do my best to comply with the lifestyle counseling provided by my doctor and his or her staff, including proper diet, exercise, stress reduction and smoking cessation.

Unless my doctor determines that I should be removed from the study for good cause or unless I decide to stop treatments myself, I intend to participate in the study and be followed for two and one half to three years after enrollment.

- C. Further blood and urine tests will be done every 5 to 10 treatments to check my kidney function. Cholesterol and other blood studies will be repeated after 30 treatments and at 6, 12, and 24 months in the maintenance phase, requiring several tubes of blood to be drawn. This will be a required part of the Registry if I am in-Group B, but similar testing will be done if I am in Group A for my safety and to monitor my progress.

For both groups, questionnaires will be done before treatment, at the end of the basic course, and at the end of 6, 12, and 24 months of maintenance. If I am in Group B, brachial artery elasticity and echocardiogram testing will be done prior to treatment, after 30 treatments and after 24 months of maintenance.

D. My chelating physician will monitor my status and results as the program proceeds, collecting lab data, clinical observations and other information and will maintain these in appropriate records. My chelating physician will inform my primary physician of my participation and progress in this Registry. I will also sign a release so that my chelating physician can obtain pertinent past medical records.

IV. Potential benefits of EDTA chelation therapy

The benefits that I hope will occur include the reduction of my chances of having heart attacks, strokes, and other major events caused by coronary artery disease, including premature death. In addition, if I have chest pains, fatigue and other symptoms that may be related to my heart, they might improve.

V. Potential risks and side effects of EDTA chelation therapy

A. Kidney strain

Serious kidney problems or other serious side effects with chelation therapy are extremely rare using the modern protocols that closely monitor kidney function. However, I realize that there

is potentially a small risk of kidney damage. I understand that it is important to do the laboratory tests to monitor my kidneys, in case my treatment regimen needs to be changed by my physician. It is especially important that I inform my treating doctor in detail about any previous kidney problems that I have suffered.

B. Thrombophlebitis

There is a possibility of less than 1% that I might suffer soreness or redness over the vein where the needle is inserted. This could progress to red streaks up my arm. My physician should be notified immediately at the first sign of concern. However, the condition is not usually serious, and relief can usually come soon with the application of warm wet compresses.

C. Lowering of blood sugar levels

There is a possibility that my blood sugar might become lowered during intravenous EDTA therapy. If I am diabetic, this might require careful attention to my condition during treatment. I agree to cooperate fully with such monitoring. Low blood sugar during treatment can almost always be prevented by eating a small snack during the treatment.

D. Low blood pressure

If I feel lightheaded or dizzy, especially right after a treatment, I understand that I need to sit back and recline in the chair. I will notify the nurse. The most likely cause is a failure of my blood pressure to adjust when I stand up. Such a problem is usually easily corrected by raising my feet and relaxing a few minutes.

E. Generalized complaints

I understand that there might be some generalized, bothersome, though not serious complaints that might develop, such as: nausea, diarrhea, numbness, muscle cramping, headaches, and low grade fever. I will notify the nurse and the doctor if they occur.

F. Fatigue

I understand that I might experience, during the course of chelation therapy, a feeling of general fatigue, which could be related to a lowering in my body of basic mineral levels, such as zinc, manganese, magnesium, and chromium. Fatigue might also be due to the body's using most of its available energy to carry out the biochemical processes stimulated by the treatment with less energy left over for daily activities. This fatigue typically becomes less as more treatments are given, and in fact most patients report a net increase in energy during chelation. If I have prominent fatigue or if my fatigue seems to be getting worse, I will notify the nurse and my chelating doctor for his or her evaluation and treatment.

G. Pain near the insertion of the needle during the infusion

Pain while the IV is flowing might occur. It is not dangerous, but it can be bothersome. I understand that I may request that my chelating doctor add a medication, such as lidocaine to reduce localized pain, if the discomfort is excessive.

VI. Alternatives to this treatment

I understand that there are alternative treatments and/or procedures for reducing the risk of coronary artery disease, which might be appropriate and available depending on my individual condition. These alternatives include:

A. No treatment at all.

There may be substantial risk associated with this choice.

B. Lifestyle changes only.

This program would consist of smoking cessation, dietary changes, and perhaps nutritional supplements, an exercise program, and attempts to deal with excessive levels of stress.

C. Drug therapy.

A common treatment for coronary artery disease is long-term drug therapies. These include long-acting nitrates or calcium channel blockers, to dilate blood vessels and improve blood flow to the heart; beta-blockers, to reduce the work load of the heart and to help prevent a second heart attack; lipid lowering drugs to reduce the cholesterol levels in the blood; and drugs like aspirin, to help reduce the clotting tendency. If I want more information on these drugs, I will ask my treating physician. If I am already taking any of these medications, I will not stop them without first consulting with one of my physicians and informing my chelating physician. I understand that it may be dangerous to stop medications abruptly without medical supervision.

D. Surgery

There are various kinds of cardiovascular surgical procedures. The most common are bypass surgery, to create surgical detours around blockages, and balloon angioplasty, to try to crush the plaque against the arterial wall, and stents, to shore up the crushed plaque. I understand that these procedures might be of substantial benefit in certain circumstances, but also carry significant risks in themselves. They do not change existing risk factors for developing coronary artery disease. If I am interested in any of these procedures, I will ask one of my physicians for more information. I will ask for a referral to a surgical specialist in this field, if I am seriously considering these options.

VII. Contacting a physician outside the office

My chelating physician will answer my questions regarding this research project specifically and my rights as a research subject, at times that are mutually agreeable. I may contact him through his office telephone (), answering service (), or pager (). In the event that I experience any worsening of my condition during the time I am a participant in this Registry or suffer any cardiac event, I understand that I should contact my chelating physician and if needed go to the nearest emergency room.

The Medical Monitor for this study is _____. I understand that I may contact the Monitor to report any complications or ask safety questions, realizing that he cannot discuss any specific medical aspects of my case because he does not have a physician-patient relationship with me.

The pager or telephone number for the Monitor is ().

The Coordinating Investigator for the Registry is L.Terry Chappell, MD, who resides in Bluffton, Ohio. His phone number is (800-788-4627).

VIII. Voluntary participation

I understand that my participation in this Registry is voluntary and that refusal to participate will involve no penalty or loss of benefits to which I might otherwise be entitled. I understand that it is my option to stop at any time this treatment protocol without reprisal or condition and to incur no further expense after I have directed my treatment to stop.

IX. Confidentiality

I understand that the confidentiality of my records will be protected as provided by law. The data from my medical chart that will be used for research purposes will be identified only by my initials and a numeric code. I give consent for the use and publication of this data. I also understand that the ACAM IRB, the GLCCM IRB, the FDA, the Medical Monitor, the Coordinating Investigator and their representatives will have the authority to inspect my medical records to confirm that what is presented is accurate and to confirm statistical accuracy. Any changes in the use of the information obtained other than that to which I have consented will first be presented to me for my approval, to the extent provided by law.

X. Costs of participating in the Registry

Costs to participating patients in the Registry include the usual charges for a history and physical exam, office visits, and appropriate laboratory, Xray and procedural charges. IV chelation therapy will be charged at usual IV treatment bottle rates, and supplements will also be provided at the usual charge. I agree to be personally responsible for those charges. Insurance company reimbursement for physician services will depend on my coverage, and I fully understand that many insurance companies do not cover treatment that is considered 'experimental'. There will be no additional charges to me just because I am participating in this Registry.

XI. Payments to me

I understand that no compensation for participation in this Registry will be provided to me by my chelating doctor, his office, ACAM or the GLCCM IRB. I also understand that neither ACAM, GLCCM nor the IRB has a policy to medically treat or compensate for physical injuries that might be incurred as a result of participating in biomedical or behavioral research. I understand that my chelating doctor is the provider of medical service in this Registry and that ACAM merely serves as the sponsor and collector of data for the project. I specifically waive and relieve ACAM, GLCCM, and the members of the ACAM and GLCCM IRBs from any responsibility for any injuries I might incur as a result of participating in this Registry.

XII. Advertisements

I understand that I will be shown copies of any advertisements used specifically to recruit patients from my area to participate in this study. These advertisements need to be approved in advance by the IRBs.

XIII. Pregnancy

I understand that the safety of EDTA treatment in pregnancy has not been established and that

my participation in this Registry may involve risks to the embryo, the fetus or to me which are currently unforeseeable if I am female and I should become pregnant. Thus I will avoid pregnancy while I participate in this Registry.

XIV. New findings

I understand that, if significant new findings develop during the course of this research which might relate to my willingness to participate, I will be provided with this information by my chelating physician and/or by the chief investigator for the Registry or one of his delegates.

XV. Copy of consent

I understand that I will receive a copy of this signed consent form.

XVI. Publication of results

In the event that the results of this project are published in a scientific journal and/or presented at a medical conference, I grant permission for my data (information) to be included, provided that my identity is protected and not published.

PATIENT'S AGREEMENT TO TESTING AND TREATMENT

As a patient of the above mentioned physician, I have had the information in this disclosure and consent form explained to me. I have had the opportunity to ask any questions of my physician as they relate to the details of this document, the Registry, and all procedures expected to be utilized.

I have reviewed and considered the information contained in this document and the information provided to me through my conversations with my treating physician and I understand that there are no warranties or guarantees of successful treatment.

Patient's Name _____
(Printed or typed)

Patient's Signature _____

Date _____

Witness _____
(Printed or typed)

Witness Signature _____

Date _____