Informed consent

A PROSPECTIVE MULTICENTER INTERNATIONAL RANDOMIZED STUDY
"Stress Echo for Ischemic Mitral Valve Surgery (SURVIVE)"

The researcher:_____

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General information

You are invited to participate in an international multicenter scientific study. An employee of the research center or a medical researcher will tell you in detail about the procedure. Information about the study is also provided in this consent form. After you get acquainted with the information provided, you will have the opportunity to ask the researcher any questions and get additional explanations.

Your consent to participate in the study is completely voluntary. You are free to either agree to participate in the study or refuse to participate. Once you have agreed to participate in the study, you may terminate your participation in the study at any time without giving any reason.

This document may contain medical terms or phrases that you do not understand. In this case, please contact your research doctor or other research center staff for clarification. If you have any other questions, please ask. Before making a decision, you can take an unsigned copy of the consent form and consider the information, discuss it with family members, friends, or your doctor. If you agree to participate in this research, you will be required to sign this consent form. This procedure is defined as obtaining informed consent.

Purpose of research

This study is conducted in order to identify and clarify indicators for operations due to secondary ischemic mitral valve insufficiency, and also contributes to the development of effective methods of surgical treatment of mitral valve pathology in patients with coronary heart disease.

Information about the study

In recent cardiac surgery and cardiology, there has been increased discussion regarding reliable indicators for surgical intervention in mitral valve pathology of varying degrees of severity if the patient requires coronary artery bypass grafting (CABG), as well as the need for intervention in the presence of mitral valve disease. To date, no reliable indicators for operations in a given situation have been established and all available recommendations have a level of evidence "C". The purpose of this study will be an attempt to answer these questions.

You are invited to participate in a prospective multicenter international randomized scientific study, which will examine the results of the implementation and/or failure of surgery for mitral valve disease in combination with coronary heart disease. You WILL NOT be undergoing new and/or experimental methods of research and/or surgery. All manipulations used in this study are officially authorized for use by the Ministry of Health of the Russian Federation and are standard in everyday medical practice.

This clinical study will include patients who may need surgery on the mitral valve per existing recommendations. The patients will then be randomized and divided into several groups. Once again, we emphasize that the operations and manipulations used in this study are well studied and have been used in standard cardiac surgery for many years.

In the course of the study, you will have regular cardiological examinations by a cardiologist, a standard echocardiographic examination of the heart on an expert class Vivid 9 echocardiograph and stress echocardiography. In case of detection of signs of acute cardiovascular insufficiency, you will immediately be assigned appropriate treatment, regardless of which group of patients you have been assigned initially.

After the end of the study, the results obtained in each group will be compared. This will allow evaluations and/or clarifications on indicators for mitral valve surgery in patients with coronary heart disease.

Study design

1. The study includes patients who have been scheduled to have CABG performed and have given informed consent to participate in the study.

2. After standard transthoracic echocardiography patients will be divided into two groups.

- Group-1 – non-massive severe mitral valve insufficiency

  (ERO - 0.2-0.39 cm2 and regurgitation volume of - 30-59 ml)

- Group-2 – massive severe mitral valve insufficiency

  (ERO ≥ 0.4 cm2 and regurgitation volume of ≥ 60 ml)

3. Patients in Group-1 will be randomly selected for operations on the mitral valve. Patients not selected will undergo no operations on the mitral valve.

4. All patients will undergo stress echocardiography (Groups-1 and Groups-2) for assessment of pathological severity.

5. One (1) year after the operation, the clinical condition of the patient will be assessed by a cardiologist, and using standard transthoracic echocardiography and stress echocardiography.

6. Three (3) years after surgery, the patient's clinical condition will be assessed by a cardiologist, and using standard transthoracic echocardiography and stress echocardiography. At the end of the study, the results obtained in each group will be compared. This will allow researchers to evaluate/clarify indicators for mitral valve surgery in patients with coronary heart disease.

Inclusion criteria for all projects are:

1. Age > 18 years
2. Ischemic MR, ERO ≥ 0.2 cm2 and RV ≥ 30 ml.
3. Indication for CABG

Exclusion criteria for all projects are:

1. Unwillingness to give informed consent and to enter a regular follow-up program.
2. Contraindications for stress echocardiography.

Possible Risks

Possible adverse events associated with the risk of surgery, increased duration of intervention and/or additional manipulation of the heart.

Possible Benefits

1) The benefits of participating in this study is that you will be under constant supervision of a specialized cardiologist such that in the case of signs of acute cardiovascular insufficiency or arrhythmia, you will be immediately prescribed appropriate specialized treatment as soon as possible.

2) Diagnostics will be carried out using safe methods. Regular monitoring according to the plan and supervision of specialists of the clinic will allow the identification of possible complications that develop in a number of patients after cardiac surgery; will allow the correction of drug therapy to be carried out, taking into account the extended diagnosis. Three (3) years after surgery, the clinical condition of the patient will be assessed by a cardiologist and using standard transthoracic echocardiography and stress echocardiography at the end of the study. The results obtained in each group will be compared. This will allow researchers to evaluate and clarify indicators for mitral valve surgery in patients with coronary heart disease.

Participation in the study

You will have to regularly and as prescribed, maintain contact with the cardiologist throughout the study, make timely visits for observation, step-by-step final visits, and follow all recommendations given.

You will need to promptly inform the doctor/researcher about all changes relating to your health (acute diseases, exacerbations of chronic diseases, injuries, pregnancy, etc.); coordinate the prescription of any drugs and non-drug treatments not specified in advance of the primary evaluation.

At any stage of the study, your participation in it may be terminated for medical reasons, if you do not comply with the doctor's recommendations and the rules of the study, and/or at your request.

Your participation in this study is voluntary.

Privacy

All data received about you by the researcher is confidential. In all reports and publications on the results of the study the anonymity of patients will be strictly observed. Primary documentation on the study, including identification of patients can be provided for inspection only to state entities having the appropriate authority.

Consent to participate in the study

By signing below, you are acknowledging that you have read all the information provided in this document, have understood it, and have agreed to participate in the study. You agree to follow the instructions that will be given to you in this study and to interact with the research physician as indicated. At any stage of the study, your participation may be terminated for medical reasons, if you do not comply with the doctor's recommendations and the rules of the study, and/or at your own request. You confirm that you have had sufficient time to ask questions about the study and that you have received satisfactory answers. You understand that this is a scientific study and that your participation in it is voluntary.

_____

Patient's name (printed in block letters)

_____ Date _____

Signature of patient

Supporting statement of the researcher

I have provided the research participant with information that I believe is accurate and to enable him/her to understand the nature, risks, and possible benefits of participating in the study and his/her rights as a research participant. I was a witness to the signing of this document by the participant of the study.

_____

Full name of the researcher (in block letters)

_____ Date _____

Researcher's signature