

RANDOMIZED PROSPECTIVE SINGLE-CENTER

RESEARCH “Surgery of Secondary Tricuspid Regurgitation-STRONG”

Date 06/06/2018

physician-researcher: _____

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General information

You are invited to participate in scientific research. A research center employee or physician-researcher will tell you about all the procedure details. Information about the study is also presented in this form. After reading further provided information, you will have the opportunity to ask researcher any questions and get additional clarifications.

Your agreement to participate in the study is completely voluntary. You are free to make your choice and can both agree to participate in the study and refuse to participate. After you have agreed to participate in the study, you can, at any time, without giving any reasons, stop participating in the study.

Perhaps this document contains medical terms or phrases that you do not understand. In case of unclear expressions, please ask for clarifications physician -researcher or another employee of the research center. If you have any other questions, please ask them. Before you make a decision, you can take an unsigned copy of the consent form home to think about the information received and discuss it with family members, friends, or your doctor. If you agree to take part in this scientific study, you will need to sign this form of consent. This procedure is defined as obtaining informed consent.

Aim of study

This study aim is to identify and clarify indications for tricuspid valve defects surgery, and also helps developing effective methods of tricuspid valve pathology surgical treatment.

Study Information

In recent years, cardiac surgery and cardiology have begun an active discussion, talking about problem of indications for surgical intervention with tricuspid valve pathology, as well as necessity of surgery with a tricuspid valve defect. Today, no reliable indications have been found in this case, all available recommendations have "C" level of evidence, and it is also not known whether the intervention is necessary. Perhaps with help of this study it will be possible to answer these questions.

You have a hemodynamically significant defect of aortic valve and / or mitral valve and / or indications for aorto-coronary bypass surgery.

You are invited to take part in a randomized, prospective clinical research study, during it results of the performed surgeries and cases with non-surgical treatment of tricuspid valve defect will be studied. You are NOT going be performed "new", "experimental" surgery. All manipulations used in this study are officially approved for use by the Ministry of Health of the Russian Federation and standardly used in everyday medical practice.

Approximately 200 patients will be included in this clinical study who may need tricuspid valve surgery according to existing guidelines. Then the patients will be randomized and divided into several groups: group of patients who will undergo surgical treatment of tricuspid valve defect according to the existing recommendations; and a group of patients when surgical treatment of tricuspid valve defect is not needed due to guidelines. We emphasize once again that the manipulations are well studied and used in everyday cardiac surgery for many years, already.

During the study, you will receive regular cardiac examinations by a cardiologist, echocardiographic examination of the heart will be performed on the expert class echocardiograph Vivid 9 using new Speckle tracking method. In case of acute cardiovascular insufficiency, you will immediately have appropriate treatment, no matter to what group of patients you initially referred.

After the end of the study, the results obtained in each of the groups will be compared. It can help evaluate / clarify the indications for operation on the tricuspid valve.

Study design

Estimated duration of the study - 3 years

Inclusion criteria

1) signed informed consent, 2) diagnosed aortic or mitral heart disease, 3) age > 18 years, 4) moderate or severe secondary tricuspid insufficiency.

Research procedures and examinations

1) Signing informed patient consent.

2) Cardiological part of the study:

1st visit - before surgery

- Consultation of a cardiologist
- Special Echocardiography

Cardiac stage (operation)

2nd visit to cardiologist - before discharge

- Consultation with a cardiologist
- Special echocardiography

3rd visit to cardiologist - 1 year after surgery

- Special echocardiography

4th visit to cardiologist- 3 years after surgery

- Special echocardiography

Possible risks

Possible risks are associated with the risk of surgery, surgical duration increase, additional manipulations with heart.

Possible benefits

1) You will be under the constant specialized supervision of a cardiologist, who, if you have any sign of acute cardiovascular insufficiency, will allow you to have the appropriate specialized treatment as soon as possible.

2) Advanced diagnostics will be performed using safe and new ultrasonic methods. More often echocardiography and examinations will reveal possible complications common to a number of patients after surgical treatment of aortic / mitral defects, coronary artery bypass surgery; will allow correction of drug therapy due to advanced diagnostics.

Participation in the study

During the entire study, you have to keep in touch with the cardiologist regularly (as it is prescribed), come to all the visits, follow all the recommendations.

You will need to inform the research doctor about any changes concerning to your health (acute diseases, exacerbations of chronic diseases, injuries, pregnancy, etc.); to tell the research doctor about all non-pharmacological treatment methods and medications you are going to use, not specified in advance at the initial intake.

At any stage of the study, your participation in it can be terminated for any medical reasons, if the recommendations of doctor researcher are not followed or if you wish.

Your participation in this study is voluntary.

Confidentiality

All data obtained by the investigator about you is confidential information. All reports and publications of study results, will be published with incognito patients status. Initial research documentation, including patient ID cards, can be provided for inspections only by government officials who have the appropriate authority.

Consent to participate in the study

By signing this document, you agree that you have read all the information presented in this document, understood it and agreed to participate in the study. You agree to follow the instructions that you will be given in this study and to interact with the research physician. At any stage of the study, your participation in it can be terminated for any medical reasons, if doctor recommendations and research regulations are not followed or if you wish. You confirm that you had enough time to ask all questions about the study, and that you received all answers and they satisfied you. You understand that this is a scientific study, and that your participation in it is voluntary.

Your full name (in blocked letters)

Your sign

Date _____

Investigator's Confirmation Statement

I provided the research participant with information on the study, which, in my opinion, is accurate and sufficient to enable him to understand the essence, risks and possible benefits of participating in the study and his / her rights as a research participant. I was (a) a witness to the signing of this paper by a research participant.

Your full name (in blocked letters)

Date _____

Your sign