

Evidence of the Advantages of Preoperative Intra-aortic Balloon Pump in Surgical Revascularization of Acute Myocardial Infarction

Brief Title: Use of Intra-aortic Balloon Pump Before Surgery for Acute Myocardial Infarction

NCT number: NCT06468982

Document date: May 1, 2021



INFORMED CONSENT FORM FOR ADULT PATIENTS

Name of Research Project: Evidence of the Advantages of Preoperative Intra-aortic Balloon Pump in Surgical Revascularization of Acute Myocardial Infarction

Name of the Responsible Investigator: Ümit ARSLAN, MD, Assoc. Prof

Name of Other Researchers: Eyüp Serhat Calık, MD, Assoc Prof.

You have been invited to take part in a study titled "Evidence of the Advantages of Preoperative Intraaortic Balloon Pump in Surgical Revascularization of Acute Myocardial Infarction". The reason you were invited to this study is because you have coronary artery disease. This study is conducted for research purposes and participation is voluntary. We would like to inform you about the research before you decide to participate in the study. Once you are fully informed about the study and your questions are answered, you will be asked to sign this form if you wish to participate. This research was conducted in the Department of Cardiovascular Surgery, Dr. Ümit Arslan is under the responsibility.

What is the purpose of the study; How many people other than me will participate in this study?

A heart attack occurs as a result of the blockage of the vessels that feed the heart muscle, called coronary arteries. In some patients, an operation called coronary bypass is a more suitable option for the treatment of blocked vessels. In a heart attack, a marker called "TROPONIN", which indicates damage to the heart muscle, increases in the blood, and in some patients, a catheter called an intra-aortic balloon pump (IABP) based on some indications is placed through the inguinal artery (femoral artery) to support the nutrition of the heart muscle. This study includes patients who had a heart attack and were decided to undergo surgery. Our aim is to compare the results between patients who receive IABP support and those who do not. All patients who had a heart attack and were decided to undergo surgery will be included in this study.

Should I participate in this study?

Whether or not you take part in this study is entirely up to you. Even if you sign this form now, you are free to stop working at any time without giving a reason. If you do not want to participate or leave the study, your doctor will apply the most appropriate treatment plan for you. Likewise, the doctor conducting the study may decide that it will not be beneficial for you to continue the study and exclude you from the study, in which case the most appropriate treatment will be selected for you.

What awaits me if I participate in this study?

Since you had a heart attack (myocardial infarction), your angiography was evaluated by the cardiovascular surgery and cardiology council. Since the council decided to perform coronary bypass surgery, your laboratory tests will be studied during the preparation for the surgery. Some blood tests of patients receiving IABP support and patients not receiving IABP support will be compared. For example, the rate at which your daily measured troponin level decreases will be evaluated. Additionally, the results of patients after bypass surgery will be evaluated between both groups.

Does study have risks?

If you are included in the study, you will not be given any extra action. only the results will be compared between the two groups. There are no risks associated with the study, other than the risks declared to you by our clinic regarding the surgery to be performed in the coronary artery bypass surgery informed consent form.



How much does it cost for me to participate in this study?

You will not be under any financial burden by participating in the study and you will not be paid any money.

How will my personal information be used?

Your study doctor will use your personal information to conduct research and statistical analysis, but your identity will be kept confidential. Only when necessary, ethics committees or official authorities may review information about you. At the end of the study, you have the right to request information about your own results. Study results may be published in the medical literature at the end of the study, but your identity will not be disclosed.

(Declaration of Participant/Patient)

At Atatürk University, Department of Cardiovascular Surgery, Dr. Ümit ARSLAN stated that a medical research would be conducted and the above information about this research was conveyed to me and I read the relevant text. After this information, I was invited as a "participant" to such a research.

I have not encountered any coercive behavior regarding my participation in the research. I also understand that if I refuse to participate, this will not harm my medical care or my relationship with the physician. I can withdraw from the research without giving any reason during the execution of the project. (However, I am aware that it would be appropriate to inform the researchers in advance that I will withdraw from the research in order not to put them in a difficult situation). I may also be excluded from the research by the researcher, provided that there is no harm to my medical condition.

I do not bear any financial responsibility for the expenses incurred for the research. No payment will be made to me either. I know that the confidentiality of personal information about me obtained from the research will be protected.

I have understood in detail all the explanations given to me. Under these conditions, I agree to participate in the clinical research in question voluntarily, with my own consent, without any pressure or coercion. İmzalı bu form kağıdının bir kopyası bana verilecektir.

Participant
Name and surname:
Address:
Phone:
Signature:
Date:
Physician meeting with participant
Name, surname, title:
Address:
Phone:
Signature: