

**INFORMATION FOR THE PATIENT  
AND  
INFORMED CONSENT**

**Verification of Safety of Early Discharge (up to 72 hours) in Low Risk Patients after Acute ST-Segment Elevation Myocardial Infarction Treated with Primary Percutaneous Coronary Intervention (PCI).**

(NCT02023983)

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**NAME OF PATIENT:**

Dear Sir, Dear Madam:

**Introduction**

The purpose of this Informed Consent form is to provide a survey of information which you will need to decide whether to take part in this research or not.

This is a clinical study, one of the types of research studies in medicine. It includes only those persons who decide to participate in it.

Please take your time to read the following information and ask questions about anything you find unclear.

After the physician conducting the study responds to all your queries, you can decide whether to take part in this study or not. The process is called Informed Consent. You will receive one copy of the form for your personal use.

Thank you for your decision to read the text.

**What is the aim of the study?**

The current recommendations of expert authorities present a possibility of discharge from hospital after having suffered certain types of myocardial infarction (as in your case also) in a chosen group of patients as early as within 72 hours after admission. This is the case of the so called low risk patients. The risk is very carefully evaluated by the treating physician, on the basis of the success rate of the intervention by which your coronary artery was treated at the beginning of your hospitalization and also on the clinical state during the hospitalization, on the results of the check-up (laboratory, ultrasound). The aspect of good cooperation on the side of the patient is also very important. Thus, the aim of the study is to learn whether also in our conditions is such an early discharge feasible, safe and is not connected with a higher rate of complications in comparison with patients who – according to the current practice – have been discharged later (usually on the fourth – seventh day after their admission).

### **Why do we ask you to participate in the study?**

The reason is that you meet the requirements which enable your inclusion in the above mentioned category of low risk patients. With these patients, assumingly, the early discharge from hospital after myocardial infarction is possible and safe.

This procedure is not in contradiction with valid recommendations of expert societies such as the European Society of Cardiology or the Czech Society of Cardiology.

### **Do I have to participate in the study?**

Your participation in the study is absolutely voluntary. If you decide, having read the text of the study, to take part, we will ask you to sign the Informed Consent form.

However, if you change your mind and decide to drop out of the study, you can do so without having to explain your reasons for this step. Your decision not to take part or to drop out will have no consequences on the quality of the medical care provided to you.

### **How will the study be organized?**

At the beginning of the study you will be randomly (by chance, like flipping a coin) assigned to one of the two groups described below, in a ratio of 1:1. The inclusion in one of the groups can not be influenced by yourself nor by your physician.

The patients randomly included in group A will not be discharged later than 72 hours after the admission. On the second and fourth day they will be summoned for a check-up of their current state of health in our outpatient clinic. Afterwards, they will be transferred to ambulance care, in accordance with their personal choice – in our Ostrava Municipal Hospital, or to any other cardiological ambulance in other hospitals (for example, in the vicinity of their residence).

The patients randomly included in group B will be discharged and transferred to ambulance care in accordance with the current common practice and decision of the treating physician (most frequently on the fourth – seventh day).

All participants will be controlled under the terms of the study after one month and three months from the date of the onset of the myocardial infarction – either by telephone or during the check-up in the cardiological ambulance. The anticipated number of patients engaged in our centre is between 80 and 100.

It is necessary to emphasize that the participation in the study has no influence on further care which is provided to all the patients after a heart attack: it does not concern the medication taken, neither the check-ups recommended by your general practitioner or cardiologist, nor further regular controls.

The only difference between the two monitored groups is the time spent in the hospital.

It is evident that one of the crucial prerequisites for the participation in the study is good cooperation between the patient and the investigating physician.

### **What are the risks for participants in the study?**

Each patient who has suffered a myocardial infarction faces a higher risk of consequent complications in comparison with the "healthy" population – such as increased occurrence of various cardiovascular events, including death. The rate of risk is varied and can distinctly differ from low to high in reliance on many factors.

As mentioned above, your individual risk rate of such attacks has been evaluated as low.

We presume – and the results of current scientific research carried out in the Czech Republic and abroad, and also our own experience suggest – that the risk of adverse events with the selected patients who will be discharged as early as 72 hours after the admission will not be higher in comparison with the analogous group of patients discharged later.

Our aim is to scientifically prove the validity of this assertion also in our conditions.

**What are the rights of participants in the study?**

The participation in the study is voluntary and depends fully on your decision. You can decide not to enrol in the study at all, and you may drop out any time you like. Your premature termination of your participation will have no consequences on the quality of the medical care provided to you.

**What are my duties?**

If you agree with the participation in the study, you will have to

- adhere to the curative regime
- cooperate on controls as planned in the study

In case you decide to interrupt your participation in the study, you will inform your physician about this fact.

**Do the participants in the study get paid?**

The study itself is not supported by any extra financial sources. Neither the participating patients nor the investigating physicians are remunerated for their participation in the study.

**Will my participation in the study be kept secret?**

All the information concerning your participation in the study will be kept secret as required by the respective law or guidelines, and will not be made public. If the results of the test are published in medical journals or discussed during sessions, they will not include any personal data of the patients. Your name will not be published either. Only the physicians carrying out the study, the medical personnel involved in it, the local medical bodies, auditors or members of Ethics Committees can directly research your medical record and information gathered during the test. Your signature on the Informed Consent form is a proof of your approval of such approach.

**What will happen to the results of the research study?**

The results will be published. However, you will not be identified in any report or publication. In the future, these results may influence the treatment of patients with a diagnosis similar to yours.

**CONSENT WITH PARTICIPATION  
AND  
PERSONAL DATA RETENTION**

If you agree with the participation in the study, you also approve of the following steps:

- 1) I confirm that I have read and understood the Information for the Patient and Informed Consent document and I was allowed to ask any questions.
- 2) I am aware that my participation is voluntary and that I can terminate it at any time without specifying any reason, without any detriment to my rights for medical care and/or to my legal rights.
- 3) I am aware that the responsible workers involved in the study, representatives of control authorities and Ethics Committees can have access to that part of my medical documentation which is connected with my participation in the clinical evaluation. I give my permission for these workers to have direct access to my medical documentation.
- 4) I agree with the gathering, transferring, processing and archiving of my personal data including the state of health in connection with the conducted study.
- 5) I agree with my participation in this clinical evaluation.

**To be filled in by the patient in his/her own handwriting:**

<b>Date of signature:</b>	<b>Signature:</b>
<b>Patient's name in block letters:</b>	

**To be filled in by the informing physician in his/her own handwriting:**

**I confirm that I have provided the patient with clear information and have responded to all his/her questions in compliance with the Information for the Patient and Informed Consent:**

<b>Date of signature:</b>	<b>Signature:</b>
<b>Physician's name in block letters:</b>	

**Informed Consent**

**Clinical Evaluation: Verification of safety of early discharge (up to 72 hours) in low risk patients after acute ST-segment elevation myocardial infarction treated with primary PCI**