



Servizio Sanitario Regionale  
**AZIENDA OSPEDALIERO – UNIVERSITARIA**  
**"Ospedali Riuniti" di Trieste**  
Ospedale di rilievo nazionale e di alta specializzazione  
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**DAI CARDIOVASCOLARE - Direttore: prof. Gianfranco Sinagra**  
**SC Cardiologia - Direttore: prof. Gianfranco Sinagra**

**S.S. EMODINAMICA ED INTERVENTISTICA CORONARICA – Responsabile dr. A. Salvi**

NUMERI TEL. DI RIFERIMENTO  
Segreteria 040 399 4865  
Segreteria Sala Emodinamica 040 399 4988;  
Degenza Cardiologia 040 399 4871 - 040 399 4899

## **INFORMED CONSENT FORM**

### **Information regarding the procedure of CORONARY ANGIOPLASTY IN ACUTE MYOCARDIAL INFARCTION**

I, the undersigned ..... born on .....  
Confirm that I have been informed on (date) ..... by Dr. ....  
THAT I AM SUFFERING FROM: **ACUTE MYOCARDIAL INFARCTION.**

### **AND THAT THE NECESSARY TREATMENT FOR THIS CONDITION REQUIRES EMERGENCY (IMMEDIATE) CORONARY ANGIOPLASTY**

The physician who has been treating you believes that your disorder has been caused by sudden occlusion of an artery responsible for supplying blood to part of the cardiac muscle (coronary artery), thus triggering a myocardial infarction. In such situations, the best treatment involves rapid reopening of the occluded artery which can be achieved by the administration of drugs and/or an emergency coronary angioplasty.

In the latter case, with local anaesthesia, a thin tube is inserted into the femoral artery (at the inguinal level) or radial artery (at the wrist level) and guided up to the heart. Following injection of a contrast medium, an X-ray identifies the occluded artery which is visualized on a screen similar to a TV. After having exactly located the area to be treated, a guide wire and then a small probe (catheter) with a small balloon are guided beyond the occluded spot. Inflation of the balloon will determine reopening of the vessel and resumption of the blood flow in the treated coronary branch. The procedure will then be completed by implanting a small metal prosthesis (stent) shaped like a net and which contributes to keeping the treated coronary branch open.

Reopening of the coronary branch by means of coronary angioplasty is a safe and effective technique. The success rate is over 90%. Reported pre-op symptoms will disappear or diminish. This treatment, furthermore, makes it possible to limit any permanent heart damage, improve the prognosis and increase the survival probability of the treated patients.

In the opinion of the clinicians who are treating you, during the angioplasty procedure in the course of a myocardial infarction, it may be necessary to position a probe (catheter) in the vein to treat cardiac arrhythmias (temporary pacemaker) or to control pressure inside the cardiac chambers (hemodynamic monitoring with a Swan-Ganz catheter). In some cases, it may be necessary to sustain circulation by applying a balloon in the artery which will help the heart push the blood into the coronary arteries (aortic counterpulsation). The clinicians and health care staff who are assisting you will manage these situations in the most appropriate manner.

At the end of the procedure, you will be required to stay in bed for the time necessary to remove the arterial introducer (small tube) and to finish stabilizing the vessel (generally, 24 hours). This time may be shorter in case of radial puncture (on the wrist). The physician will be able to assess the possibility of using a different method of stabilization (haemostasis) which will allow you to move sooner, or to use an anticoagulant therapy, which guarantees the same therapeutic efficacy of manual compression at the puncture site. These systems rarely induce infection (approximately 5 cases out of 1,000.)

#### **Predicted outcomes due to lack of treatment:**

It should be emphasized that failure to undergo the procedure of emergency angioplasty places the patients at a higher risk, resulting from a clinical situation which has not been adequately treated

#### **The most common risks of this procure are:**

The risks deriving from the dilation procedure are limited. In concrete terms this means that the risk of death deriving from this procedure is very small (2/5 out of 1,000). The need for emergency aortic coronary bypass is rare (less than 1 case out of 100, in our experience). Other rare complications deriving from the coronary angioplasty procedure involve damage on the artery at the inguinal level; embolic complications with consequent cerebral stroke, renal or intestinal damage; cardiac arrhythmias; contrast medium-induced renal failure. The latter, at times associated to renal embolus, can determine severe renal failure requiring dialysis. Haemorrhagic complications (from bleeding) are more frequent when the angioplastic procedure is performed after having attempted to use drugs to reopen the occluded coronary branch, that is, with a thrombolytic drug, or during infusion of antithrombotic drugs, administered to improve flow inside the treated vessel. These events are often transient or are resolved with pharmacologic treatments; they rarely require surgery,

### **SPECIAL WARNINGS**

#### **IODINE ALLERGY**

The procedure may require administration of a contrast medium that contains iodine. Those subjects who have had previous allergic reactions following administration of iodine or who have undergone angiographic investigations must follow a special medical treatment (pre-medication with antihistamines and cortisone) during the prior 24 hours.

**Known allergy to IODINE**      **NO** ☐:      **YES** ☐

#### **PREGNANCY**

Due to the use of X-rays, the clinician must be informed of any pregnancy or possible current pregnancy.

THE PROCEDURE WILL BE PERFORMED BY ONE OR MORE OF THE FOLLOWING CLINICIANS: dr. Alessandro Salvi, dr.ssa Fulvia Longaro, dr. Andrea Perkan, dr.ssa Serena Rakar, dr. Giancarlo Vitrella.

THE REFERENCE PHYSICIANS IS DR::.....

**I was given the opportunity to ask questions and I feel that the above information and any further clarifications requested have been sufficiently complete. .**

Patient signature\*.....      Clinician signature.....      Date.....

\* the patient, even if a minor, must always signs

**I, THE UNDERSIGNED** .....

### AUTHORIZE / DO NOT AUTHORIZE the above-indicated procedure

Patient signature\* .....Date.....

I AUTHORIZE/DO NOT AUTHORIZE the clinician to perform any additional procedures considered necessary by the clinician during the procedure (for example, intracoronary ultrasound, aortic counterpulsation, invasive monitoring by means of a Swan Ganz catheter, temporary implant of a pacemaker) in the sole interest of my health and for a better success of the procedure itself.

Patient signature\* .....Date.....

### TO BE SIGNED IF THE PATIENT IS A MINOR

Father's signature..... Mother's signature.....

Date.....Date.....

### INFORMATION PROVIDED TO THE PATIENT BY MEANS OF AN INTERPRETER

Name and last name of the interpreter (print).....

Interpreter's signature .....document.....Date.....

Name and last name of the witness (print).....

Witness signature .....document.....Date.....

Name and last name of the witness (print).....

Witness signature .....document..... Date.....

### USE OF BLOOD OR HEMODERIVATIVES

I confirm that on (date) ..... Dr..... mi ha informed me about the possibility, in case of significant bleeding, of the need to receive a blood transfusion or transfusions of its derivatives and was informed especially regarding the risk of infection with transmission of Hepatitis B,C, or HIV or any allergic reactions. I was furthermore informed about possible alternatives to the transfusion and the risks deriving from refusal of such transfusion.

I authorize , if required, blood transfusions and/or its derivatives.

Patient signature\* ..... Physicians signature.....Date.....

Father's signature.....Mother's signature..... Date.....

(in case of minors)

\* the patient, even if a minor, must always sign