AF42 Informed Consent for Human Research, Second Zhejiang Medical Hospital

Dear patient:

We invite you to participate in a clinical study that Compare the Long-Term Clinical Efficacy of IVUS and Angiography Guidance PCI for Acute STEMI before you decide whether to participate in this study to help you understand the study and why the study, procedures and duration, the benefits, risks and inconvenience you may bring from the study.

Here is an introduction to this study:

I. Research Background and Research Purpose

Intravascular ultrasound (IVUS) has been increasingly used for selective and emergency percutaneous coronary intervention. Recent randomized controlled studies, large-scale registration studies, and meta-analysis have demonstrated significant advantages in reducing mortality, myocardial infarction, and target revascularization compared with separate angiographic-guided angiography.

However, the results of previous clinical study of IVUS guiding PCI in acute myocardial infarction (AMI) have few clinical data, and the results are still controversial. This study will explore the effects of IVUS-guided PCI on clinical outcomes in patients with acute ST-segment elevation myocardial infarction (STEMI).

二、Specific procedures and processes

1. research time: the ethical approval of each center starts until December 31,2024;

2. follow-up: We will receive clinical evaluation on days 30,6,12,2, and 3 years after surgery.If the patient does not come to the hospital on schedule, email contact can be acceptable via phone.

III. What do you need to do for the research

The researchers will ask for record, record your previous history and medication, and conduct a physical examination. You also need to cooperate with blood drawing for relevant laboratory tests, cooperate with other laboratory tests such as electrocardiogram and coronary angiography, and improve the IVUS examination according to the randomization situation. If you agree to join this study, you also need to sign an informed consent to visit our hospital for clinical follow-up.

IV. Potential benefits from participating in this study

In this study, you will conduct rigorous clinical observation and examination during preoperative and postoperative follow-up to facilitate a better understanding of your condition and a more timely and reasonable treatment; IVUS guided coronary disease intervention has been scientifically proven to bring significant benefits to patients and is currently a routine surgical procedure.

V. Potential adverse reactions, risks and risk prevention measures for participating in this study

Complications measured by IVUS include coronary dissection, thrombosis, lateral branch occlusion, artery rupture / perforation, and embolization. In daily clinical work, using IVUS to detect the extent of stenosis was a routine surgical procedure and there was no additional risk in this study.

VI. Cost Description

Compared to angiography guidance: the coronary ultrasound catheter costs $ 8400 and $ 3300 for surgical treatment. IVUS guided intervention of coronary heart disease is a routine surgical procedure, and the examination has entered the medical coverage, so this study does not substantially add additional costs.

VII. Compensation for participating study, including compensation for damage

All the treatment examination measures involved in this study, including IVUS examination and postoperative follow-up, were routine coronary heart disease intervention, with no additional medical burden and additional medical risks.

VIII. Alteratives

The medical measures involved in this study are the routine treatment measures for patients with coronary heart disease. If the patients do not participate in this study, we will continue the routine PCI or drug treatment according to the clinical guidelines.

IX. Confidentiality of your personal information

Your medical records (including research medical records and physical and chemical examination reports) will be kept in the hospital as required.In addition to the investigator, the Ethics Committee, the supervision, inspection, drug administration department, and other relevant personnel who will be allowed to access your medical records, those unrelated to the study are not entitled to access your medical records without permission.The public report of the results of this study will not

disclose your personal identity. We will do every effort to protect the privacy of your personal medical information within our permission.

X. Termination of Participation in the Study

Participation in this study depends entirely on your voluntariness. You may refuse to participate in this study or quit the study at any time during the process, which does not affect your relationship with your doctor or the loss of your medical or other interests.In addition, your participation in this study may be terminated for the following reasons:

1, You did not follow the research doctor's advice.

2, You have had a serious condition that may require treatment.

3, research doctors believe that terminating the study is most beneficial for your health and benefits.

XI. The Ethics Committee

This study has been reported to the Human Research Ethics Committee of the Second Affiliated Hospital of Zhejiang University School of Medicine, and was approved after a comprehensive review by the committee and including the risk assessment of the subjects. In the course of the study, ethics and equity can contact the HR Ethics Committee of the Second Affiliated Hospital of Zhejiang University School of Medicine, daytime: 0571-87783759; evening (general duty): 13757118366; E-mail address: HREC2013@126.com

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I confirm that I have read and understood the informed consent form of this study, voluntarily accepted the treatment methods in this study, and agreed to use my medical data for the publication of this study.

Subject's signature:_____Contact information:_____Date:_____

Signature:_____Relations with the subjects_____Contact information

Date:_____

(If required)

Witness (if required): Contact information:_____Date:_____

I confirm that the details of the study, including its rights and possible benefits and risks, and were given a copy of the signed informed consent form.

Investigator Signature:_____

Contact information:_____(Mobile Phone) Date:_____