An Exploratory Study of Effectiveness and Safety of Rivaroxaban in Patients With Left Ventricular Thrombus

Informed Consent Form

(Sep 10, 2020)

Trial registration This study was registered at ClinicalTrials.gov as NCT 04970381.

Research Affiliation: Fuwai Hospital, National Center for Cardiovascular Diseases, Chinese Academy of Medical Sciences and Peking Union Medical College

Preamble: Based on your medical condition and the judgment of your physician, you are invited to participate in a clinical study. If you decide to participate in this study, please read the instructions carefully, understand your role in the study, clarify the nature and risks of the study, and sign the informed consent form. This study has been reviewed and approved by an independent ethics committee. Participation in the study is completely voluntary and will not affect your treatment while in the hospital, whether or not you participate in this study.

Background and purpose of the study

Left ventricular thrombus is often secondary to acute myocardial infarction and cardiomyopathy, and if left untreated, thrombus dislodgement can lead to serious embolic complications such as stroke. Compared with warfarin, rivaroxaban, a new oral anticoagulant has had good efficacy and safety in previous studies because of its rapid onset of action and the lack of frequent laboratory tests. The aim of this study was to evaluate an effective and safe anticoagulation strategy for left ventricular thrombus.

Study plan

This study plans to select 60 patients receiving rivaroxaban for an exploratory study over 1-1.5 years. If your disease condition meets the criteria for inclusion in this study, you may voluntarily sign the informed consent form after the investigator has fully communicated with you and you have been informed of the study risks. Hematological indicators such as routine blood, biochemistry, and coagulation function will be collected before your first dose, at 6 weeks and 12 weeks follow-up, according to clinical routine, to evaluate contrast-enhanced echocardiography, and to record thrombus size, anticoagulant use and the occurrence of endpoint events. The specific medication is a standard dose of atrial fibrillation anticoagulation of rivaroxaban 20mg qd (reduction to 10-15mg qd may be considered in special cases) under the guidance of your physician. Follow-up treatment will be determined by the investigator after 12 weeks based on your condition. In addition, we will follow up with you in the office or by phone 6months after enrollment, regarding the name of the person who answers and the relationship with you, collection of events such as embolism, bleeding, and anticoagulant use. These visits may take up some of your time and may cause you problems or inconvenience.

Risks and benefits

The drug involved in this study is mainly rivaroxaban, and the common adverse effects are mainly bleeding in a lower percentage of cases. Any adverse events that occur to you will be treated promptly and in strict accordance with authoritative clinical guidelines. We guarantee that all your diagnostic and therapeutic work will never be affected by the need of the study and that

you will be informed of the results of our study in a timely manner.

Fees and Compensation

This study is a clinical observational program in which the investigator will provide you with medication instruction and follow-up. The medications involved throughout the study are routinely used in clinical practice, and there is no additional cost to you for participating in this study.

Damage Compensation Clause

If you experience any discomfort during the study, you may contact the investigator at any time for appropriate guidance. The study drug is a common post-marketing drug that is used in accordance with clinical practice and does not additionally increase your risk, therefore no compensation is provided.

Rights and confidentiality principles

Information obtained from this study will likely be published, but your name will be kept strictly confidential. No personal and private information about you will be disclosed to anyone other than members of the research team and ethics committee to ensure that your reputation and dignity are not violated.

Ethics Committee

This study has been approved by the hospital ethics committee. If you have further questions, you may consult with the investigator or contact 010-88396281.

Signature Page

I acknowledge that I have read and understood the informed consent form for this study, voluntarily participate in the study, and agree to the associated academic publication.

Sign: Tel: Date:

If a family member signs for you, name and relationship:

Sign: Tel: Date:

Physician/researcher:

Sign: Tel: Date: