Ethics Committee of the Third Xiangya Hospital of Central South University

Rapid review of approved cases

Lot No.: Express 25231

Name of pilot project	Analysis of risk factors for microcirculatory obstruction after PCI in patients with acute myocardial infarction		
applicant	Xiangya Third Hospital of Central South University		
research organization	Xiangya Third Hospital of Central South University	Project category	Non-registered clinical studies
administrative division	cardiovascular medicine	Principal Investigator	XXX
Type of review	Initial review	examiner	XXX
Review of documentation	See annex for details		
voting result	☑ Agreed☐ Agreed with necessary modifications ☐ Converted to sessional review		
Opinion of the Ethics Committee	not have		

Review of resolutions	After review, consent was granted to conduct this clinical study. Will the conduct of this study be subject to regular follow-up review by an ethics committee? Yes The frequency of follow-up review of this study by the Ethics Committee will be every 12 months from the date of approval. The study should be initiated within one year from the date of approval, and if it is not initiated after that date, the approval shall be revoked. If the study is not completed within the frequency of follow-up review, please submit an application for regular follow-up review to the Ethics Committee one month before the expiration of the approval, and the Ethics Committee has the right to change the frequency of follow-up review according to the actual progress. Ethics Committee of Xiangya Third Hospital of Central South University (Seal) March 28, 2025

relevant note	1. Declaration: The duties, composition, operation and records of this Ethics Committee follow the international ICH-GCP, Measures for Ethical Review of Biomedical Research Involving Human Beings, Code of Practice for Quality Management of Pharmaceutical Clinical Trials, and other relevant Chinese laws and regulations. 2. Principles to be followed: Please strictly follow the principles of medical ethics in the course of clinical trials and effectively protect the rights and interests of the subjects. Any modification or change to the clinical research protocol, informed consent form, recruitment materials, other materials for subjects, etc. during the course of the study should be reported to the Ethics Committee in a timely manner, and can be implemented only after obtaining the written approval of the Ethics Committee. 3. Safety report: any events related to the safety of subjects during the trial shall be reported to the ethics committee and relevant departments in accordance with GCP and other relevant regulations and the requirements of the study protocol. 4. Follow-up review: The Ethics Committee is authorized to conduct regular follow-up reviews of ongoing clinical trials, the frequency of which should be based on the level of risk to the subjects. 5. If the content involves the protection of human genetic resources or must be approved by the relevant departments in accordance with national regulations, it shall be implemented only after it has been approved or recorded by the relevant departments. 6. For projects involving prior review, when the applicant receives the clinical trial notification issued by the State Drug Administration, if it is a conditional opinion or involves the revision of the research program, the applicant shall submit the notification of the State Drug Administration and the relevant revised documents to the Ethics Committee for review and approval before implementation. 7. Contact: Ethics Committee, Third Xiangya Hospital of Central South University Address: No. 138 Tongzipo, Yuelu District, Changsha, Hunan Province, China Tel: 0731-88618938

attachment (email)

Name of pilot project	Analysis of risk factors for microcirculatory obstruction after PCI in patients with acute myocardial infarction
batch number	Fast 25231

Review of documentation

1. research program (version number: 1.0, version date: February 27, 2025)
2. Research Program Signature Page (version number: 1.0, version date: February 27, 2025)
3. Informed consent for data collection (version number: 1.0, version date: March 1, 2025)
4. Scientific validity review form (version number: NA, version date: NA)
5. XXX GCP Certificate (Version No.: NA, Version Date: NA)
6. Resume of the researcher - XXX (version number: NA, version date: NA)
7. XXX Practicing Certificate (Version No.: NA, Version Date: NA)
8. List of research team members (version number: NA, version date: NA)
9. Description of products not involving pharmaceutical products (version number: NA, version date: NA)
10. XXX-Principal Investigator and Research Team Conflict of Interest Statement (Version No. NA, Version Date: NA)