Heji Hospital Affiliated to Changzhi Medical College

Ethical review approval document

Item Name	**Comparison of the long-term effects of three therapeutic schemes for sever MGD**	Approval Number	K25-030
Research Category	※Scientific Research：☐Interventional Study ☑Observational Study※Other_____		
Project Source	**National Project☐ Provincial Project☐ Municipal Project☐ Hospital-level Project☐ Multicenter Collaboration Project☐ Other Project☑**		
Principal Investigator	Guo Xuming	Department	
Review Method	☐Full Board Review ☑Expedited Review		
Review Date	2023.4.28	Location of Review Meeting	
Review comment	Review Decision：☑ Approved ☐ Approved after Necessary Revisions ☐ Re-review after Necessary Revisions ☐ Disapproved **In accordance with the ethical principles outlined in the National Health Commission's "Ethical Review Measures for Life Sciences and Medical Research Involving Humans," the Chinese Hospital Association's "Guidelines for the Construction of Ethics Committees for Clinical Research Involving Humans," the WMA's "Declaration of Helsinki," and the CIOMS's "International Ethical Guidelines for Health-Related Research Involving Humans," this ethics committee has reviewed and approved this study to be conducted according to the approved clinical research protocol and informed consent form.** **Please adhere to GCP principles, follow the protocol approved by the ethics committee, and protect the health and rights of the subjects.** **If there is any change of the principal investigator, or any modifications to the clinical research protocol, informed consent form, etc., the applicant must submit an application for amendment review.** **In the event of any serious adverse events, the applicant must promptly submit a serious adverse event report.** **Please follow the tracking review frequency stipulated by the ethics committee. The applicant must submit a progress report one month before the deadline. If any situation arises that may significantly affect the conduct of the trial or increase the risk to subjects, the applicant must promptly submit a written report to the ethics committee.** **If any non-compliance/violation of the research protocol occurs during the research process, or any situation that may adversely affect the rights/health of the subjects or the scientific validity of the research, constituting a violation of GCP principles, the sponsor/monitor/investigator**		

	must submit a non-compliance/protocol violation report. **If the applicant suspends or terminates the clinical research early, a suspension/termination report must be submitted promptly.** **Upon completion of the clinical research, the applicant must submit a study completion report.** **This trial must be initiated within 1 year after approval. This approval document will automatically become void if the trial has not been initiated by the deadline.**
Tracking Review Frequency	☐3 months ☐6 months ☑12 months
Ethics Committee Seal	seal Date: