

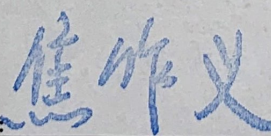
The Second Hospital of Lanzhou University Medical Ethics Committee approved

Project number:2019A-231

Project Name	A real-world study of recurrent pregnancy loss in China		
Sponsor	The Second Hospital of Lanzhou University		
Project Leader	Fang Wang		
Declare Department	Department of Reproductive Medicine	Research members group	Fang Wang, Kehu Yang, Sigong Zhang, Xiaobin Hu, Fangxiang Mu, Zhuhua Cai, Jinhua Fu, Ligui Xiong, Zhongjie Guo, Lirong Du.
Type of project	Retrospective study		
Review categories	First review	Review form	Meeting review
Review materials	Application forms, research protocols, informed consent forms, etc.		
Meeting time	October 29, 2019	Meeting venue	Conference room, 23 rd floor, Building 2, Inpatient Department, the Second Hospital of Lanzhou University
Chief adjudicator	Zuoyi Jiao, Jing Yang, Guangdi Li, Chaoming Ge, Yajie Wei, Hongwen Zhu Jing He, Wei Ren.		
Review result	Pass after making necessary corrections		
Track review frequency	12 months		
Review comments	The experts of the Medical Ethics Committee of the Second Hospital of Lanzhou University listened to the report of the project team, and conducted ethical review, questions and questions on the qualifications of the researchers, the project research plan, the informed consent of the tested patients in the actual (trial) test, the privacy protection of the subjects, the operation process and other aspects. The responsibilities, composition and working procedures of the Medical Ethics Committee of the Second Hospital of Lanzhou University comply with the principles of GCP and relevant national laws and regulations. The ethics experts attending the meeting voted according to the review and unanimously agreed to carry out the study in accordance with the approved research protocol and informed consent. Chairman of committee: Zuoyi Jiao Review data: October 29,2019		

兰州大学第二医院医学伦理委员会审批件

项目编号: 2019A-231

项目名称	中国反复妊娠丢失的真实世界研究		
申办单位	兰州大学第二医院		
项目负责人	王芳		
申报科室	生殖医学科	课题组成员	王芳、杨克虎、张思功、胡晓斌、牟方祥、蔡珠华、付锦华、熊丽桂、郭仲杰、杜丽荣
项目类型	☒ 回顾性研究		
审查类别	☒ 初审 ☐ 复审	审查形式	☒ 会议审查 ☐ 快速审查
审查材料	申请表, 研究方案, 知情同意书等		
会议时间	2019 年 10 月 29 日	会议地点	兰州大学第二医院住院部 2 号楼 23 楼会议室
主审委员	☒ 焦作义 ☐ 白锋 ☐ 余静 ☒ 葛朝明 ☒ 李光迪 ☒ 王旭 ☒ 杨静 ☐ 魏志红 ☒ 韦亚洁 ☒ 朱宏文 ☒ 贺婧 ☒ 任伟		
审查结论	☐ 通过 ☒ 做必要的修正后通过 ☐ 做必要的修改后再议 ☐ 不通过 ☐ 终止 ☐ 暂停已批准的试验 ☐ 回避		
跟踪审查频率	☒ 3 个月 ☐ 6 个月 ☒ 12 个月 ☐ 不适用		
审核意见	兰州大学第二医院医学伦理委员会专家听取了项目组的汇报, 对研究者资格, 项目研究方案, 实(试)验中受试患者创伤知情同意、补偿、受试者隐私保护, 操作过程等方面进行了伦理审查、提问和质疑。兰州大学第二医院医学伦理委员会的职责、人员组成和工作程序符合 GCP 原则及国家相关法律法规。参会伦理专家根据审查情况进行了投票表决, 一致同意按所批准的研究方案、知情同意书等开展本研究。  主任委员: <u>焦作义</u>  审核单位: (盖章) 医学伦理委员会 审核时间: 2019 年 10 月 29 日		



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