Ethics Committee of Beijing University of Chinese Medicine

Approval Notice Template

Project No.: 2022BZYLL1017

Project Name: Effectiveness and safety of the infrared ceramic graphene moxibustion device for knee osteoarthritis: a Zelen-design randomized controlled non-inferiority clinical trial	
Main Researcher: Han Li	Project Classification: National Key R&D Project "Researches on Modern Chinese Medicine"
Bidding Unite: College of Traditional Chinese Medicine, Beijing University of Chinese Medicine	Contract Research Organization(CRO):
Approval Classification: Primary Approval	Approval Methods: ☐Quick Approval ☑Conference Approval
Approval Committee Member: See Attachments	Approval Date: September 29, 2022
Approval Document(Specify the version and date): Research Protocol(Version No.: V2.0; Version Date:2022.10.11) Informed Consent(Version No.:V2.0; Version Date: 2022.10.11)	
Approval Basis: According to the *Medicine Good Clinical Practice, GCP* (2003), *Medical Device Good Clinical Practice, GCP* (2016) of CFDA, the *Declaration of Helsinki* (2013) of World Medical Association, the *International Ethical Guidelines for Biomedical Research on Human Subjects* (2016) of CIOMS, and the Reviewing Measures for Ethics of Biomedical Research Involving Human Subjects (No. 11, 2016) of National Health and Family Planning Commission.	
Approval Decision: Agreed	
Notes: 1. This approval is valid for one year from the date of issue, from 17 October 2022 to 17 October 2023. The researcher must strictly use the approved and agreed Informed Consent and Research Protocol. 2. The applicant must complete the clinical trial registration before the start of the research. 3. Any research project involving Chinese human genetic resources and requiring approval must be advised that it can not commence until receiving the approval from the Chinese Office of Human Genetic Resources Management. 4. If there is a change of principal researcher during the study, or any modification to the clinical research protocol, informed consent, recruitment materials, etc., the applicant should submit an amendment approval application. 5. In case of serious adverse events, the applicant should promptly submit a serious adverse event report. 6. Please follow the annual/regular follow-up review frequency specified by the Ethics Committee, and the applicant shall submit study progress reports 1 month before the deadline. 7. For situations such as the studies include subjects who do not meet the inclusion criteria or meet the exclusion criteria, conforming to discontinue the trial while fail to withdraw the subjects from the study, the studies that fail to carry out researches according to the protocols, such as giving the wrong treatment or dose, or giving a combination of drugs prohibited by the protocol, or situations that violate the GCP principles, adversely influencing the rights/health of the subjects and the scientific validity of the study, the sponsor/supervisor/researcher should submit a report of breaching the protocol. 8. If the applicant suspend or terminate the clinical study in advance, please promptly submit a report on the suspension/termination of the study. 9. To complete the clinical research, the applicant is requested to submit a closing report.	
Chairman of Committee☑Vice Chairman of Committee☐Signature:  Ethics Committee of Beijing University of Chinese Medicine The continuous approval frequency of the project is ☐3 months☐6 months☑12 months	Time: October 17, 2022 Conference Location: Online Conference Contact: Li Mei, Zhao Lihong (010)53911431

Seal: Medical and Animal Ethics Committee of Beijing University of Chinese Medicine

北京中医药大学医学伦理委员会

Ethics Committee of Beijing University of Chinese Medicine

伦理审查批件

Approval Notice Template

项目编号：2022BZYLL1017

项目名称：红外陶瓷石墨烯艾灸仪治疗膝骨性关节炎的有效性和安全性观察——项基于 Zelen's 设计的随机对照、非劣效性临床研究

主要研究者：韩丽	项目类别：国家重点研发计划“中医药现代化研究”
申办单位：北京中医药大学中医学院	合同研究组织（CRO）：
审查类别：初始审查	审查方式：□快速审查☑会议审查
审查委员：见附件	审查日期：2022 年 9 月 29 日

批准文件（注明版本号及日期）：研究方案（版本号：V2.0，版本日期：2022. 10.11）

知情同意书（版本号：V2.0，版本日期：2022. 10.11）

审查依据：根据 CFDA《药物临床试验质量管理规范》（2003 年）、《医疗器械临床试验质量管理规范》（2016 年）、世界医学会《赫尔辛基宣言》（2013 年）、国际医学科学组织委员会《人体生物医学研究国际伦理指南》（2016 年）、国家卫生计生委《涉及人的生物医学研究伦理审查办法》（第 11 号，2016）等。

审查决定：同意

注：

1、本批件自签发日期有效期一年，2022 年 10 月 17 日至 2023 年 10 月 17 日，研究者必须严格使用经审查同意的知情同意书和研究方案。

2、研究开始前，请申请人完成临床试验注册。

3、凡涉及中国人类遗传资源、需要报批的研究项目，需告知在获得中国人类遗传资源管理办公室批准后才能开始。

4、研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。

5、发生严重不良事件，请申请人及时提交严重不良事件报告。

6、请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告。

7、研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验而未让受试者退出研究。给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者/监查员/研究者提交违背方案报告。

8、申请人暂停或提前终止临床研究，请及时提交暂停/终止研究报告。

9、完成临床研究，请申请人提交结题报告。

主任委员☑副主任委员□签字：

时　间：2022 年 10 月 17 日

北京中医药大学医学伦理委员会

会议地点：线上会议

本项目持续审查频率□3 个月□6 个月☑12 个月

联系人：李梅、赵丽红（010）53911431