- **Original Ethical Approval Certificate**

中国人民解放军陆军军医大学第一附属医院伦理委员会
临床试验审查批件

批件号：（A）KY2023188

项目名称	经皮脊髓直流电刺激对前交叉韧带重建术后功能恢复的有效性和安全性的随机、对照、单中心临床试验研究
试验分类	□注册药物　□注册器械　■临床科研　□其他
临床分期	药物适用：□I 期　□II 期　□III 期　□IV 期　□其他： 器械适用：□临床试用　□临床验证　□其他：
组长单位	无
申请科室	康复医学科
主要研究者/职称	侯景明/副主任医师
审查意见	评审说明： 本伦理委员会于 2023 年 11 月 21 日对该项目研究方案、知情同意书等有关材料进行了会议审查，结果为“作必要修正后同意”（详见“2023 年 11 月 21 日会议评审修改通知”）。研究者修改后再次递交，伦理委员会经快速审查认为总体上：研究项目成员资格具备，送审资料完备，临床研究方案、知情同意书等材料符合伦理要求，同意进行以上项目的临床研究。
	评审结论：同意
	持续审查频率：□3 个月　□6 个月　■12 个月　□其他：
批准材料	1. 初审申请表 2. 复审申请表 3. 研究方案（版本号：V6.0　日期：2023.12.18） 4. 知情同意书（版本号：V2.0　日期：2023.12.12） 5. 病例报告表（版本号：V3.0　日期：2023.12.12） 6. 主要参考文献 7. 主要研究者专业履历（GCP 证书） 8. 科学性审查批件

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批件有效期	根据本研究预期研究周期 3 年，批件的有效期从批准之日至 2026 年 12 月 24 日。

注意事项（请仔细阅读）：

1. 请遵循 GCP 原则，按照本伦理委员会批准的方案开展临床研究；
2. 未经伦理委员会批准，主要研究者及研究方案、知情同意书、招募材料等与受试者相关的文件不得作任何变更；若需修改，须以修正案的形式提交伦理委员会，获批准后执行；
3. 本中心发生严重不良事件请及时提交“严重不良事件报告”；
4. 请按照本批件规定的持续审查频率，提前 10 个工作日提交“研究进展报告”；
5. 研究过程中出现严重方案违背、持续方案违背，请提交“方案违背报告”；
6. 若需暂停或提前终止临床研究，请及时提交“暂停/终止研究报告”；
7. 若研究超过本批件的有效期，需提前 10 个工作日向本委员会提交“研究进展报告”，经伦理委员会审查批准后可继续进行；
8. 研究结束时，须提交“结题报告表”供伦理委员会进行审查。

主任委员（或副主任委员）签名：

中国人民解放军陆军军医大学第一附属医院伦理委员会（盖章）

日期：2023 年 12 月 25 日

申明：本伦理委员会的组成及工作程序符合国家卫生和计划生育委员会《涉及人的生物医学研究伦理审查办法（2016 年）》，国家药品监督管理局、国家卫生健康委员会《药物临床试验质量管理规范（2020 年）》、《医疗器械临床试验质量管理规范（2022 年）》，WMA《赫尔辛基宣言》，CIOMS《人体生物医学研究国际道德指南》，ICH GCP 中的相关要求及伦理准则。

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● **English Translation of the Ethical Approval Document**

Ethics Committee Approval Letter for Clinical Trial

The First Affiliated Hospital of Army Medical University, People's Liberation Army of China

Approval Number: (A)KY2023188
Study Title: A Single-Center Randomized Controlled Trial on the Efficacy and Safety of Transcutaneous Spinal Direct Current Stimulation for Functional Recovery After Anterior Cruciate Ligament Reconstruction
Trial Category: ☐Registered Drug ☐Registered Medical Device ☑Clinical Research ☐Other
Drug Applicability: ☐Phase I ☐Phase II ☐Phase III ☐Phase IV ☐Other
Device Applicability: ☐Clinical Trial ☐Clinical Validation ☐Other
Leading Institution: Southwest Hospital, Third Military Medical University (Army Medical University)
Applying Department: Department of Rehabilitation Medicine
Principal Investigator/Professional Title: Hou Jingming/Associate Chief Physician

Review Opinion

Review Notes: The Ethics Committee conducted a conference review on the study protocol and relevant materials of this project on November 21, 2023, with the result of "Approved with Necessary Revisions" (see details in the "November 21, 2023 Conference Review Revision Notice"). After the investigators submitted the revised materials, the Ethics Committee conducted an expedited review and confirmed that: the research team is qualified, all submitted materials are complete, and the clinical study protocol, informed consent form and other documents comply with ethical requirements. The committee hereby approves the conduct of this clinical study.
Review Conclusion: Approved
Continuous Review Frequency: ☐Every 3 months ☐Every 6 months ☑Every 12 months ☐Other

Approved Materials

Initial Review Application Form
Re-review Application Form
Study Protocol (Version No.: V6.0; Date: December 18, 2023)
Informed Consent Form (Version No.: V2.0; Date: December 12, 2023)
Case Report Form (Version No.: V3.0; Date: December 12, 2023)
Key References
Principal Investigator's Professional Resume (including GCP Certificate)
Scientific Review Approval Letter

Validity Period of Approval Letter： Based on the study's anticipated 3-year duration, the approval letter is valid from the date of approval to December 24, 2026.

Notes (Please Read Carefully)

1.Conduct the clinical study in compliance with Good Clinical Practice (GCP) principles and strictly in accordance with the protocol approved by this Ethics Committee.

2.Without prior approval from the Ethics Committee, no modifications shall be made to the principal investigator, study protocol, informed consent form, recruitment materials, or any other documents related to participants. If revisions are required, a formal amendment must be submitted to the Ethics Committee and implemented only after approval.

3.In the event of a Serious Adverse Event (SAE) occurring at the institution, promptly submit a "Serious Adverse Event Report".

4.In line with the continuous review frequency specified in this approval letter, submit a "Study Progress Report" 10 working days in advance.

5.If any major or persistent protocol deviations occur during the study, submit a "Protocol Deviation Report" immediately.

6.Should the clinical study need to be suspended or terminated prematurely, promptly submit a "Study Suspension/Termination Report".

7.If the study exceeds the validity period of this approval letter, submit a "Study Progress Report" to the Ethics Committee 10 working days in advance. The study may continue only after obtaining approval from the Ethics Committee.

8.Upon completion of the study, submit a "Study Completion Report Form" for review by the Ethics Committee.

Ethics Committee of the First Affiliated Hospital, Army Medical University, People's Liberation Army of China

Date: December 25, 2023

Declaration

The composition and working procedures of this Ethics Committee fully comply with the relevant requirements and ethical guidelines stipulated in: Measures for the Ethical Review of Biomedical Research Involving Humans (2016) issued by the National Health and Family Planning Commission; Good Clinical Practice for Drugs (2020) and Good Clinical Practice for Medical Devices (2022) jointly issued by the National Medical Products Administration and the National Health Commission; the World Medical Association (WMA) Declaration of Helsinki; the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Humans; and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP).

Contact Information

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