甘肃省人民医院科研伦理意见函

Research Ethics comment letter of Gansu Provincial Hospital

编号：2024-781 lot number: 2024-781	会议日期：2024 年 12 月 27 日 Date of meeting: Fri, Dec 27, 2024
伦理委员会：甘肃省人民医院伦理委员会 Ethics Committee: ethics Committee of Gansu Provincial Hospital	
研究方案名称：D-SPECT 对高血压合并 INOCA 患者心肌灌注成像及冠状动脉血流储备的临床评估 English Name：Clinical study of myocardial perfusion imaging and coronary flow reserve by D-SPECT in patients with hypertension combined with INOCA.	
主要研究者及所属科室：王楠，甘肃省人民医院，心内科干部病区 Major investigator and affiliated departments: Nan Wang, Department of Cardiovascular, Gansu Provincial Hospital, Lanzhou, China.	
审查文件：临床研究项目具体方法、知情同意书等相关材料 Review documents: Research projects, informed consent and other related materials.	

同意 Agree	修改后同意 Agreed after modification	不同意 Disagree	终止或暂停 Termination or suspension	弃权 Abstained
9 票 9 votes	0 票 0 vote	0 票 0 vote	0 票 0 vote	0 票 0 vote

1. 委员会议对研究方案及知情同意书的评审意见：
   该项目符合伦理要求，同意申报。
   Committee's opinion on the research program and informed consent:
   The project meets ethical requirements and agrees to declare.
2. 根据以上意见，委员会对该方案的审查决定如下：
   同意 √
   修改后同意
   不同意
   终止或暂停试验
   Based on the above comments, the Committee's review of the programme is as follows:
   Agree √
   Agreed after modification
   disagree
   Terminate or suspend the trial
3. 该研究进行过程中将接受伦理委员会的持续审查：　　是 √　否
   The study will be subject to ongoing review by the Ethics Committee: Yes √ No
4. 审查频度为研究批准之日起每 12 月一次。
   The frequency of the review is once every 12 months from the date of approval of the study.

5. 伦理委员会有根据实际进展情况改变持续审查频度的权利。

The Ethics Committee has the right to change the frequency of ongoing reviews in the light of actual progress.

主任委员签名：

Signature of the Chairman:

医院伦理委员会（盖章）：

Ethics Committee (seal):

甘肃省人民医院 医学伦理委员会

日期：2024 年 12 月 27 日

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备注：

Note:

1 研究过程中，对研究方案和知情同意书等相关文件所作的任何修改，均须得到伦理委员会审查同意后方可实施。

During the course of the study, any changes to the relevant protocols, such as the study protocol and informed consent, must be reviewed and approved by the ethics committee.

2.本中心发生的严重不良事件或意外不良事件需 SFDA 上报的同时向伦理委员会作书面通报，伦理委员会有权根据对其评估做出新的决定。

Severe adverse events or accidental adverse events in the Center are reported to the Ethics Committee at the same time as the SFDA reports, and the Ethics Committee has the right to make new decisions based on its assessment.

3. 无论试验开始与否，请在持续审查到期前 1 个月提出再次审查的申请。

Regardless of the start of the trial, please submit an application for re-examination 1 month before the expiration of the trial.

4.试验项目若超过一年，需提交年度跟踪审查报告，当出现可能显著影响试验进行或增加试验风险情况，请申请人及时向伦理委员会提交书面报告。

If the test project exceeds one year, an annual follow-up review report shall be submitted. When there is a possibility that the test may be significantly affected or the test risk may be increased, the applicant shall submit a written report to the ethics committee in time.

证　明

兹有2022级住院医师规范化培训学员白雪莲，身份证号：622225199206222423，自2022年9月至2025年6月在我院住培基地进行住院医师规范化培训，培训专业：内科。

特此证明。

甘肃省人民医院

临床教学部

2025年1月2日