

苏州高新区人民医院

医学伦理委员会论证审查批件

The Approval Report of Medical Ethics Committee of The People's Hospital of Suzhou New District

[2023]伦审批第 003 号

受理部门：医学伦理委员会 Acceptance Department: Medical ethics committee		时间：2023 年 03 月 08 日 Date: :	
委托部门：普外科 Department: Department of general surgery		委托人：孙毅 Clients: Sun Yi	电话：13770664680 Phone number: 13770664680
论证项目名称：改良手术方式对胰十二指肠切除术临床结局的影响研究 Research title: Study on the effect of modified surgical methods on the clinical outcome of pancreaticoduodenectomy			
<p>项目材料完整性： Project materials</p> <p>申请表 <input checked="" type="checkbox"/> 主管部门批件 <input type="checkbox"/> Application forms Approval from the competent department</p> <p>技术水平/药品检查报告 <input checked="" type="checkbox"/> Technical level/drug inspection report</p> <p>设备/材料质量报告 <input type="checkbox"/> Equipment/material quality report</p> <p>知情同意书 <input checked="" type="checkbox"/> 试验研究/治疗方案 <input checked="" type="checkbox"/> Informed consent Experimental studies/treatment regimens</p>			
<p>委员会调查、听证情况： Investigation and hearing of the Committee</p> <p>技术人员水平及设备条件是否符合要求 <input checked="" type="checkbox"/> Whether the technical personnel level and equipment conditions meet the requirements</p> <p>受试者入选方案是否合理 <input checked="" type="checkbox"/> Whether the subject inclusion scheme is reasonable</p> <p>实验/医疗技术信息资料完整性、易懂 <input checked="" type="checkbox"/> Laboratory/medical technical information data integrity, easy to understand</p> <p>获取知情同意书方法是否适当 <input checked="" type="checkbox"/> Whether the method of obtaining informed consent is appropriate</p> <p>试验/治疗方案是否适当 <input checked="" type="checkbox"/> Suitability of the trial/treatment regimen</p> <p>药物、技术、设备、仪器等安全性和有效性 <input checked="" type="checkbox"/> Safety and effectiveness of drugs, technologies, equipment, instruments, etc</p> <p>受试者是否获益大于风险 <input checked="" type="checkbox"/> Whether the benefits outweigh the risks</p>			

委员会会议表决（投票）结果：

Result of voting (voting) at committee meetin:

应参会委员（11）人

实际参会委员（9）人

members shall attend the meeting (11)

Actual participants (9)

表决结果：同意

Result: Agreed

（注：表决方式为：I 同意，II 作必要修改后再议，III 不同意，IV 终止或暂停试验/医疗技术）

(Note: The voting method is as follows: i agree, ii make necessary changes and discuss again, iii disagree, iv terminate or suspend the test/medical technology)

委员会论证决议：

The Committee demonstrated the resolution:

经医院医学伦理委员会调查论证，项目“Study on the effect of modified surgical methods on the clinical outcome of pancreatoduodenectomy”

论证结果为：该实验设计符合伦理学相关法规要求，同意开展

After investigation and verification by the medical ethics committee of the hospital,

Research titled:

The results of the demonstration are: the experimental design meets the requirements of relevant ethics laws and regulations, and it is agreed to carry out.

主任委员签字

Signature of chairman.

年 月 日（盖章）

Date 2023.03.08

对否决、修改后再议结果理由说明：

Explanation of reasons for the result of veto and re-discussion after modification: