

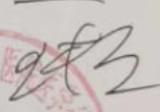
福建医科大学附属第一医院医学伦理委员会医学研究与临床应用分会审查批件

Ethics Review Form for Branch for Medical Research and Clinical Technology Application, Ethics Committee of First Affiliated Hospital of Fujian Medical University

闽医大附一伦理医技审[2015]084-1号

MTCA,ECFAH of FMU [2015]084 -1

项目名称 Protocol Title	住院病人医疗信息和生物标本的二次利用 Reutilization of Medical Information and Biological Specimens of the Inpatients		
项目来源 Protocol Source	福建医科大学附属第一医院 The First Affiliated Hospital of Fujian Medical University		
伦理审查方式 Mode of Review	<input checked="" type="checkbox"/> 会议审查 Meeting Review <input type="checkbox"/> 快速审查 Quick Review		
审查类别 Type of Review	<input type="checkbox"/> 初次审查 Initial Review <input checked="" type="checkbox"/> 修正案审查 Review on Amendments <input type="checkbox"/> 跟踪审查 Tracing Review <input type="checkbox"/> 违背方案审查 Review on Contrary to Protocol <input type="checkbox"/> 严重不良事件审查 Review on Serious Adverse Events <input type="checkbox"/> 暂停/终止研究审查 Suspending/Terminating Review on Research <input type="checkbox"/> 结题审查 Review on End of Research <input type="checkbox"/> 复审 Review		
会议地点 Meeting Location	门诊十二楼大会议室 Conference room at the 12th floor	日期 Date	2019-4-3
送审材料 Documents for Reviewing	福建医科大学附属第一医院患者住院须知 (V4.0 2019.4.3) Instructions for hospitalization in the First Affiliated Hospital of Fujian Medical University(V4.0 2019.4.3)	审查委员 Review Person	见附件 2 See Attachment 2
出席人员 Attendees	实到 Attendance: 9 人, 回避 Avoidance: 0 人		
投票情况 Voting Results	1.同意 Approval (9) 人 2.作必要修正后同意 Approval after necessary amendment (0) 人 3.作必要修正后再审 Check Review after necessary amendmen (0) 人 4.不同意 Disapproval (0) 人 5.终止或暂停已批准的技术 Terminating / Suspending the Approved Technology (0) 人		
审查意见 Comments	<p>2019年4月3日, 伦理委员会根据国家《药物临床试验质量管理规范》、《赫尔辛基宣言》及《涉及人的生物医学研究伦理审查办法》等伦理原则, 对本方案进行伦理跟踪审查, 同意在我院继续实施。</p> <p>On Apr. 3rd, 2019, According to the national ethical principles of <i>Good Clinical Practice, Declaration of Helsinki</i> and <i>Measures for the Ethical Review of Biomedical Research Involving Humans</i>, a meeting ethical review of the project was conducted, and the project is approved to be carried out in our hospital.</p>		

备注 Remarks	<p>本审查委员会声明: 遵从 ICH-GCP、中国 GCP、中国相关法规及指南的要求组成和开展工作, 其审查和工作过程不受伦理委员会以外的任何组织及个人的影响。</p> <p>本伦理委员会对本项目研究要求: 1. 完成项目研究时, 向伦理委员会提交结题报告; 2. 每年度至少向伦理委员会提交 1 次“年度进展报告”; 3. 如研究方案、知情同意书等文件的任何修改, 应及时通知伦理委员会, 必要时重新审查, 获批准后执行。4. 在批件有效期届满 1 个月前向伦理委员会提出申请。</p> <p>The Institutional Review Board (IRB) declares that: In accordance with the requirements of ICH-GCP, China GCP and relevant laws and regulations or guidelines in China, the review and other working processes are free from any influence of any organization or individuals other than this Ethics Committee.</p> <p>Requirements on researches given by the IRB to the project are as follows: 1. Submitting a concluding report to the IRB when completing researches on the project; 2. Submitting at least one “annual progress report” to the IRB each year; 3. If there is any modification on documents such as research plan or informed consent, notify to the IRB in time and do Check Review if necessary for further execution after approval; 4. Please submit an application within 30 days before the expiry date.</p> <p>主任委员签字: </p> <p>Signature of the chairman of committee:</p> <p>日期: 2019年4月3日</p> <p>Date: (YYYY/MM/DD)</p>		
批件有效期 Validity Period of Ethical Review Approval Document	2019年4月3日——2022年4月2日 3rd, April, 2019----2nd, April, 2022		
伦理委员会地址 Ethics Committee Address	福建省福州市茶中路 20 号 No.20, Chazhong Road, Fuzhou, Fujian Province	联系电话 Contact Number	0591-87981028

泉州市第一医院伦理审查意见

泉一伦【2020】105号

研究项目名称	Effect of liver inflammation on accuracy of FibroScan device in assessing liver fibrosis stage in patients with chronic hepatitis B virus infection (肝脏炎症对 FibroScan 诊断慢性乙型肝炎肝纤维化分期准确性的影响)		
拟研究时间	2014.04-2019.12		
项目负责人	余雪平	职称	主治医师
联系电话	15859455206	电子邮箱	xuepy15@fudan.edu.cn

简述与伦理有关的研究内容:

In this multi-center study, ninety-seven patients with chronic hepatitis B virus infection who accepted liver biopsy and FibroScan device examination were retrospectively included. Any discordance in fibrosis staging by FibroScan and pathological scores was statistically analyzed. Effect of different degrees of liver inflammation on the accuracy of FibroScan stage in assessing the stage of fibrosis in patients with chronic HBV infection was studied in detail. A non-invasive model was constructed to predict the risk of misdiagnosis of fibrosis stage using FibroScan.

(本研究为多中心回顾性研究, 总共纳入 97 例行肝穿刺活检及 Fibroscan 检查的慢性乙型肝炎病毒感染患者, 通过对 FibroScan 与肝组织病理评估肝纤维化分期不一致性进行统计分析, 详细地探讨肝脏炎症对 fibroscan 预测慢性乙型肝炎患者纤维化分期诊断价值的影响, 并构建包含有 Fibroscan 测的肝脏弹性指标的无创模型来预测 fibroscan 肝纤维分期错误的风险。)

审批意见:

该项研究不违背伦理原则, 同意在知情同意的前提下实施研究。

泉州市第一医院伦理委员会

2020年03月9日



福建医科大学

国家自然科学基金委员会：

经福建医科大学生物医学研究伦理审查委员会审定（[2014]福医伦理审字第（87）号），“负性共刺激分子 BTLA 在 HBV 慢性感染中的表达及作用”不违背伦理原则，同意其在知情同意的前提下实施该项研究。



福建医科大学生物医学研究伦理审查委员会
2014年3月9日
