

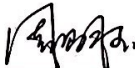
贵州医科大学附属医院医学科学伦理委员会伦理审查批件

The Ethics Committee of the Affiliated Hospital of GuiZhou Medical University

Ethics Approval Document

批件号 (Approval Number) : 2020 伦审第 (104) 号

项目名称 (Protocol Name)	TGF- β 1/Smad2/3、P38MAPK、PI3K/AKT 信号通路靶向诱导肝星状细胞 GLUT1 表达和在有氧糖酵解促进纤维化进程		
项目类别 (Protocol Source)	<input checked="" type="checkbox"/> A.基础研究 (basic research) <input type="checkbox"/> B.应用基础研究 (basic research for application) <input type="checkbox"/> C.临床研究(clinical research) <input type="checkbox"/> D.药学研究 (pharmacy research) <input type="checkbox"/> E. 新技术应用(New technology test) <input type="checkbox"/> F.限制类技术 (Restricted technology) <input type="checkbox"/> G.其他(Other) (请注明 please specify)		
申请部门 (Research Department)	感染科 Infectious department	专业负责人 (Deputy of Department)	杨京 Yang jing
项目负责人 (Principle Investigator)	周明玉 Zhou mingyu		
研究目的 (Aim of Project)	探讨 TGF- β 1 通路调控 GLUT1 影响肝星状细胞周期和活化的研究		
涉及人体研究内容 (The Contents Related to in vivo Human Study)	<p>从肝纤维化病例中选取 10 例患者，年龄 18-65 岁，诊断符合慢性乙肝、酒精性肝病、自身免疫性肝病相关指南和肝纤维化中西医结合诊疗指南，无其他器官、系统疾患；无肝脏穿刺活检禁忌症，签署知情同意书，并告知收集的样品仅用于科学研究而非商业用途。方法：肝脏组织标本采用 B 超引导下单次弹射活检针进行肝穿活检，组织长度$\geq 1.5\text{cm}$；留取两份标本，其中一份肝穿刺后标本迅速放置于含 10%中性福尔马林固定液 2ml 的冻存管中，另一份直接放入冻存管中，液氮保存，编码标记清晰。外周血采用常规肝素抗凝管抽取，新鲜分离为 PBMC 和血浆，分别液氮和-80°C冰箱保存备用。肝穿标本经 HE 染色，两名病理科医生独立进行病理学诊断，根据 Ishak 评分系统进行炎症分级、肝纤维化分期量化评分；免疫组织化学或 Westernblot 检测肝脏标本中上述相关通路涉及的各种蛋白的表达水平。蛋白质非靶组学检测代谢组分改变。</p> <p>By this study,10 patients aged 18-65 years were selected from the cases of liver fibrosis . The diagnosis was in line with the relevant guidelines for chronic hepatitis B, alcoholic liver disease, autoimmune liver disease and the diagnosis and treatment guidelines for liver fibrosis with integrated traditional Chinese and western medicine, and no other organ or system diseases were found.No contraindications to liver biopsy, signed informed consent and informed that the samples collected were for scientific research only and not for commercial use.Methods: Liver tissue samples were performed by single ejection biopsy needle guided by B-ultrasonography with tissue length $\geq 1.5\text{cm}$.Two samples were collected, one of which was immediately placed in a cryopreservation tube containing 2ml 10% neutral formalin fixation solution after liver puncture, and the other was directly placed in the cryopreservation tube and stored in liquid nitrogen with clear coding marks.Peripheral blood was</p>		

	<p>extracted using conventional heparin anticoagulant tubes, and freshly separated into PBMC and plasma, which were stored in liquid nitrogen and -80 °C refrigerator respectively for later use. Hepatic specimens were stained by HE, and two pathologists independently made pathological diagnosis. Inflammation grade and liver fibrosis staging were quantitatively scored according to the Ishak scoring system. The expression levels of various proteins involved in the above related pathways in liver samples were detected by immunohistochemistry or Western blot.</p>						
<p>可能出现的不良反应与危害和防治与补偿措施 (Possible Adverse Reactions and Hazards and Prevention and Compensation Measures)</p>	<p>肝脏穿刺术有很小概率引起患者疼痛、出血、局部感染等不良反应。本课题组选用高年资主治医师以上级别并且富有丰富临床经验者进行肝脏穿刺术, 医师在操作过程中, 会在 CT 引导下严格按照肝脏穿刺术章程实施手术, 术后严密监测患者生命体征及可能出现的症状, 避免不良反应的发生。若患者术后出现出血征象, 立即给予止血治疗, 必要时输注血浆或浓缩红细胞。局部感染者, 根据具体情况给予抗炎治疗, 尽力将不良反应降到最低。</p> <p>Liver puncture has a very small chance of causing pain, bleeding, local infection and other adverse reactions in patients. Our group selected senior attending physicians or above and rich clinical experience to perform liver puncture. During the operation, physicians will perform the operation in strict accordance with the liver puncture charter under the guidance, the operation was performed in strict accordance with the rules of liver puncture, and the patients' vital signs and possible symptoms were closely monitored after the operation to avoid the occurrence of adverse reactions. If the patient shows signs of bleeding after surgery, hemostasis treatment should be given immediately, and plasma or concentrated red blood cells should be injected if necessary. For locally infected patients, anti-inflammatory treatment should be given according to specific conditions to minimize adverse reactions.</p>						
<p>申请人(项目负责人)承诺:</p> <p>以上所填内容属实, 本人承诺待该项目批准后, 我将遵循 GCP、方案以及伦理委员会的要求, 开展本项临床研究。所有涉及人类遗传资源采集、收集、买卖、出口、出境的研究, 待获得人类遗传办批件后再开展。该批件仅用于前期立项申请, 不得用于项目启动伦理审查。</p> <p>The Promises of Applicant or Principle Investigator:</p> <p>The above contents are true. If approved, I will strictly abide by the "Articles of Association of the Human Ethics Committee of Guizhou Medical University" and conduct project research according to the provided scheme.</p> <p>该批件仅用于立项申请, 不得挪着他用, 项目获批后需再次申请伦理启动审查。</p> <p style="text-align: right;">签字(Sign):  日期(Date): 2020.3.2</p>							
<p>审查途径 Approval Category</p>	<table border="1"> <tr> <td>快速审查(Quick Review) <input type="checkbox"/></td> <td>书面审查(Written Review) <input checked="" type="checkbox"/></td> </tr> <tr> <td>会议审查(Meeting Review) <input type="checkbox"/></td> <td>会议日期(Meeting Date):</td> </tr> <tr> <td colspan="2"> <p>结论(Result):</p> <p><input checked="" type="checkbox"/> 同意 (approval) <input type="checkbox"/> 修改后同意 (approval after revising)</p> <p><input type="checkbox"/> 不同意 (disapproval) <input type="checkbox"/> 修改后重审 (Appraisal after revising)</p> <p><input type="checkbox"/> 暂停已批准的试验 (Terminate or suspend its prior approval)</p> </td> </tr> </table>	快速审查(Quick Review) <input type="checkbox"/>	书面审查(Written Review) <input checked="" type="checkbox"/>	会议审查(Meeting Review) <input type="checkbox"/>	会议日期(Meeting Date):	<p>结论(Result):</p> <p><input checked="" type="checkbox"/> 同意 (approval) <input type="checkbox"/> 修改后同意 (approval after revising)</p> <p><input type="checkbox"/> 不同意 (disapproval) <input type="checkbox"/> 修改后重审 (Appraisal after revising)</p> <p><input type="checkbox"/> 暂停已批准的试验 (Terminate or suspend its prior approval)</p>	
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审查意见(Review Recommendation):

经我院伦理委员会讨论审核, 认为该项目符合《涉及人的生物医学研究伦理审查办法(试行)》及赫尔辛基宣言关于生物人体试验的相关规定, 同意在我院收集样本开展本项研究。

After discussion or review by the ethics committee of our hospital, the project was found to be in compliance with the Ministry of Health's "《Methods for Ethical Review of Biomedical Research Involving Human Beings (Trial)》" and the relevant provisions of the Helsinki Declaration on biological human testing, and agreed to collect samples from our hospital for this research.

主任委员签字:

(Signature by the Ethics Chairman)

盖章 (Stamp)

日期(Date)



附: 申请人(项目负责人)简要信息

Attachment: Information of Applicant or Principle Investigator

姓名 (Name)	周明玉 ZHOU MINGYU	性别 Sex	女 Female	学历学位 Education Background	博士 Ph.D	职称 Title	副主任医师 Associate Chief physician
电话(Phone)	0851-86773914			E-mail	4037403@qq.com		
手机(Mobile Phone)	15086001308			邮编(Zip Code)	550004		
通讯地址 Correspondence Address	贵州医科大学附属医院感染科						
研究方向 Research Interest	肝纤维化的形成机制						

声明: 本伦理委员会的组成、职责及工作程序遵循中国 GCP 和有关法规。

地址(Add.): 贵阳市云岩区贵医街 28 号

Affiliated Hospital of GuiZhou Medical University Guiyang Guizhou 550004 P.R.China

电话(Tel.): +86 0851-86814581 传真(Fax.): +86 0851-86752685