

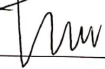
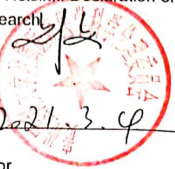
贵州医科大学附属医院医学科学伦理委员会伦理审查批件

The Ethics Committee of the Affiliated Hospital of GuiZhou Medical University

Ethics Approval Document

批件号 (Approval Number) : 2021 伦审第 (029) 号

项目名称 (Protocol Name)	miR-3682-3p/RUNX1/C-Myc 反馈环路调控肝癌干性以及 EMT 的作用机制研究 (The role of miR-3682-3p/RUNX1/C-Myc feedback loop in the stemness and EMT of hepatocellular carcinoma)		
项目类别 (Protocol Source)	<input type="checkbox"/> A. 基础研究 (basic research) <input checked="" 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)	肝胆外科	专业负责人 (Deputy of Department)	喻超 YU CHAO
项目负责人 (Principal Investigator)	左石 ZUO SHI		
研究目的 (Aim of Project)	血清学及肝癌/癌旁组织病理学方法分析 miR-3682-3p、RUNX1 两者表达相关性以及与临床预后之间的关系 Investigate the expression of miR-3682-3p and RUNX1 in a scale of clinical human HCC samples and their correlation with the patients' prognosis and tumor stage		
涉及人体研究内容 (The Contents Related to in vivo Human Study)	预计收集 50 例肝癌与 30 例健康人体肝新鲜组织研究。如果患者同意参加, 医生在获得患者的书面同意后, 将对其行肝癌切除术或肝脏穿刺活检术, 留取 5ml 血液、肝癌/癌旁组织或一条 1.8×15mm 大小肝脏组织进行相关实验检测, 根据病情需要, 进行常规复查的时候将留取相关检查及化验结果并定期随访患者病情变化。 It is expected that 50 cases of hepatocellular carcinoma with 30 cases of healthy human liver fresh tissue will be collected for the study. If the patient agrees to participate, after obtaining the patient's written consent, the physician will perform a hepatectomy or liver aspiration biopsy, retain 5 ml of blood, hepatocellular/paracellular tissue or a 1.8 x 15 mm sized piece of liver tissue for relevant experimental testing, and, depending on the condition, will retain the relevant tests and laboratory results for routine review and regular follow-up of the patient's condition.		
可能出现的不良反应与危害防治与补偿措施 (Possible Adverse Reactions and Hazards and Prevention and Compensation Measures)	(如空格填写不下, 可以附件形式附后) 癌切除术严格按照相关操作规范执行。 肝脏穿刺术有很小几率引起患者疼痛、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。		

	<p>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。 Cancer resection is performed in strict accordance with the relevant operation specifications.</p> <p>There is a small chance that liver puncture will cause adverse effects such as pain, bleeding, and local infection in patients.</p> <p>The group uses senior attending physicians or above with rich clinical experience to perform liver puncture. During the operation, the physicians will strictly follow the protocol of liver puncture under CT guidance and closely monitor the patient's vital signs and possible symptoms after the operation to avoid adverse reactions.</p> <p>If a patient shows signs of bleeding after surgery, hemostatic treatment is given immediately and, if necessary, plasma or concentrated red blood cells are transfused.</p> <p>In case of local infection, anti-inflammatory treatment is given on a case -by-case basis, and every effort is made to minimize adverse effects.</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>签字(Sign):  日期(Date): 2021. 2. 26,</p>
<p>审查途径 Approval Category</p>	<p>快速审查(Quick Review) <input type="checkbox"/> 书面审查(Written Review) <input checked="" type="checkbox"/></p> <p>会议审查(Meeting Review) <input type="checkbox"/> 会议日期(Meeting Date):</p> <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 (Terminator suspend its prior approval)</p>
<p>审查意见(Review Recommendation):</p> <p>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研究。</p> <p>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.</p> <p>主任委员签字:</p> <p>(Signature by the Ethics Chairman)</p> <p>盖章 (Stamp)</p> <p>日期(Date) 2021. 3. 4</p>	
<p>附：申请人（项目负责人）简要信息</p>	<p>Attachment: Information of Applicant or Principle Investigator</p>
<p>姓名 左石</p>	<p>性别 男 学历学位 博士 职称 主任医师</p>

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研究方向 Research Interest	肝纤维化、肝硬化、肝癌 Liver fibrosis, liver cirrhosis and liver cancer.						

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。

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