

The Second Affiliated Hospital of Guangzhou Medical University
Clinical Research and Application Institutional Review Board Approval Document
广州医科大学附属第二医院临床研究与应用伦理委员会伦理审查批件

批件号/ Approval No: 2017-ks-12 审批日期/ Approval Date: Mar. 25, 2017
地址/Address: 250 East Changgang Road, Guangzhou, Guangdong, China, 510260
电话/Tel: +86-20-34152264 传真/Fax: +86-20-34153066

Study Title: Early prediction of survival in hepatocellular carcinoma with transarterial chemoembolization plus sorafenib

Study Type: Retrospective Cohort Study

Reviewed documents: Study protocol (Version 01, Mar 15, 2017)

Review procedure: Fast-track procedure

Principle Investigator: Kang-Shun Zhu M.D.

Department: Department of Minimally Invasive Interventional Radiology

The Second Affiliated Hospital of Guangzhou Medical University Institutional Review Board has reviewed and approved the study protocol, in accordance to ICH GCP guidelines, government regulations and laws.

Conditions:

1. Do not deviate from, or make changes to the study protocol without prior written IRB approval, except when it is necessary to eliminate immediate hazards to research subjects or when the change involves only logistical or administrative issues.
2. Report the following to IRB: (1) study protocol or consent document change (2) serious adverse event (3) study progress (4) new information that may be relevant to a subject's willingness to continue participation in the study.
3. Report the study result to IRB after study closure.

IRB Chairman Signature:



Clinical Research and Application Institutional Review Board

The Second Affiliated Hospital of Guangzhou Medical University

2017-03-25



广州医科大学附属第二医院临床研究与应用伦理委员会
伦理快速审查批件

批件号: 2017-ks-12

项目名称	早期预测肝动脉化疗栓塞联合索拉非尼治疗晚期肝细胞癌的生存期 (Early prediction of survival in hepatocellular carcinoma with transarterial chemoembolization plus sorafenib)		
研究类型	回顾性研究	审查方式	快速审查
项目负责人	朱康顺 (Kangshun Zhu)	科室	微创介入科
审议文件	临床研究方案 (版本号: 01; 版本日期: 2017-03-15)		
审评意见 (可附页)	<p>经伦理委员会审查, 同意按提交文件开展本项研究。</p> <p style="text-align: right;">  主任委员 (签名):  伦理委员会 (盖章):  日期: 2017年3月25日 </p>		
<p>备注:</p> <ol style="list-style-type: none"> 参与研究单位应严格按照本伦理委员会批准的方案执行。在研究实施过程中, 如需对研究方案、知情同意书等文件做任何修改, 应及时向本伦理委员会提交更改申请, 补充更新文件, 经伦理委员会重新审查, 获准后方可执行。 发生严重不良事件及可能影响风险受益比的任何事件和新信息须及时报告本伦理委员会。 如有不依从/违背方案或暂停/提前终止的研究项目, 应及时以书面文件告知本伦理委员会; 研究结束后, 须及时向伦理委员会提交结题报告。 请参考人类遗传资源管理相关规定, 如属于需要申报范围, 请通过遗传资源管理部门批准才开展。 			

伦理委员会地址: 广东省广州市品岗东路 250 号 (510260), 电话: 020-34153599, 联系人: 谢志红, 陈娟