Review and approval of Biomedical Ethics Committee of West China Hospital of Sichuan University

2019 Audit (928)

Department (professional): Anesthesia surgery center		Study leader: Peng Liang / deputy chief physician
Study title	Effects of intravenous and inhalation anesthesia on blood glucose and complications in patients with type 2 diabetes mellitus	
Study scheme	Version number: V1.0	Version date: September 27, 2019
Informed consent form	Version number: V1.0	Version date: December 04, 2019
Recruitment advertisement	None	

Review comments:

1.The qualification of the researchers meet the ethical requirements.

2. The study scheme and informed consent form basically meet the ethical requirements.

Results of the review: ■ Approval ☐ Approval after modification ☐ Retrial after revision ☐ Disapprove ☐ Suspension or termination of research

Frequency of continuous review: ☐ 3 months ☐ 6 months ■ 1 year ☐ NA

Please follow the relevant laws, regulations and rules of our country (measures for Ethical Review of Biomedical Research involving people, etc.), as well as Declaration of Helsinki and CIOMS, to conduct clinical trials (studies) in accordance with the program and informed consent approved by the Ethics Committee to protect the health and rights of the subjects.

Please strictly follow the requirements of the interim measures for the Administration of Human genetic Resources and the guidelines for Administrative Licensing Services for the Collection, Trading, Export and exit examination and approval of Human genetic Resources. Projects of human genetic resources used for clinical diagnosis and treatment should be examined and approved by the Biomedical Ethics Committee of West China Hospital. After the approval of the ethics project, the genetic application should be submitted to the Ministry of Science and Technology of the people's Republic of China, and the online registration should be completed (the reporting process can be queried at Chengdu cd120. The enquiry telephone number is 85422851).

In the course of the trial (study), if you change the principal researcher and make any changes to the clinical research plan, informed consent form, etc., please submit the application for amendment review.

If a serious adverse event occurs, the applicant is requested to submit a serious adverse event report in time; after the emergency report, submit a detailed follow-up report of the serious adverse event as soon as possible.

Please submit annual and periodic follow-up review reports; in the event of any circumstances that may significantly affect the conduct of the trial (study) or increase the risk of the subjects, the applicant is requested to submit a written report to the Special Committee on Ethics in time.

The sponsor / inspector / researcher will be required to submit a violation report if the following occurs , subjects who do not meet the inclusion criteria or meet exclusion criteria are included , subjects who meet the discontinuation of the trial (study) but do not allow them to withdraw from the trial (study), subjects who are given the wrong treatment or dose, the combined use of drugs prohibited by the program do not comply with the program to carry out the study; Or where ethical principles and norms may be adversely affected on the rights , interests / health of the subjects, and the scientific nature of the research.

If the applicant suspends or terminates the clinical study (trial) ahead of time, please submit a report on suspension / termination of the trial (study) in time.

Clinical research cannot be carried out without ethical review and approval.

This approval is valid for one year, and if it is not implemented within the time limit, it will be annulled on its own.

According to the requirements of the International Committee of Medical Journal Editors (ICMJE), all clinical studies in the human body and using human specimens should be registered. Researchers who receive ethical approval must register with the China Clinical Research Registration Center before the start of clinical research. Please use the public account of our hospital (please send e-mail to hxlcyjglb@163.com of the Clinical Research Management Department. contact number: 85422851). Log in to the following website for clinical research registration: http//www.chictr.org.cn, the only registration number will be generated after the successful registration of the clinical research project, please send it to the Ethics Office by a text message in time, which is a required item for ethics followers to review.

Unit (Chapter):
Chairman (signature):
December 18, 2019

四川大学华西医院生物医学伦理委员会审查批件

2019年 审（928）号

科室（专业）： 麻醉手术中心	项目负责人姓名及职称: 梁鹏/副主任医师	
项目名称	全凭静脉与全凭吸入麻醉对2型糖尿病患者血糖及并发症的影响	
研究方案	版本号：V1.0	版本日期：2019年09月27日
知情同意书	版本号：V1.0	版本日期：2019年12月04日
招募广告:	无	

审查意见：

1. 研究者资质符合伦理要求。
2. 研究方案及知情同意书基本符合伦理要求。

审查结果：■批准 □修改后批准 □修改后再审 □不批准 □暂停或者终止研究

持续审查频率： □3个月/3months □6个月/6months ■1年/1year □不适用/NA

请遵循我国相关法律、法规和规章（《涉及人的生物医学研究伦理审查办法》等）以及WMA《赫尔辛基宣言》和CIOMS《人体生物医学研究国际道德指南》，遵循伦理委员会批准的方案和知情同意书开展临床试验（研究），保护受试者的健康与权利。

请严格遵循《人类遗传资源管理暂行办法》和《人类遗传资源采集、收集、买卖、出口、出境审批行政许可服务指南》的要求，对于以临床诊疗等为目而使用的人类遗传资源的项目，均应经过华西医院生物医学伦理委员会审查同意。伦理立项批准后，应向国家科技部遗传办申请报备，并完成网上注册填报（填报流程可在cd120查询，咨询电话85422851）。

在试验（研究）过程中，若变更主要研究者，对临床研究方案、知情同意书等的任何修改，请申请人提交修正案审查申请。

发生严重不良事件，请申请人及时提交严重不良事件报告；紧急报告之后，尽快提交详细的严重不良事件随访报告。

请递交年度和定期跟踪审查报告；当出现任何可能显著影响试验（研究）进行或增加受试者危险的情况时，请申请人及时向伦理专委会提交书面报告。

试验（研究）纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验（研究）规定而未让受试者退出试验（研究），给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益/健康、以及研究的科学性造成不良影响等违背伦理原则与规范的情况，请申办者/监查员/研究者提交违背方案报告。

申请人暂停或提前终止临床试验（研究），请及时提交暂停/终止试验（研究）报告。完成临床试验（研究），请申请人提交结题报告。

未经伦理审查批准,不能开展临床研究。

本批件有效期为一年，逾期未实施的，则自行废止。

根据国际医学期刊编辑委员会（ICMJE）要求，所有在人体中和采用取自人体的标本进行的临床研究均应注册。请接到伦理批件的研究者务必在临床研究开始前到中国临床研究注册中心注册，请使用我院公共账号(请发邮件到临床研究管理部邮箱hxlcyjglb@163.com申请，联系电话：85422851)登陆以下网址进行临床研究注册： http://www.chictr.org.cn,临床研究项目注册成功后产生的唯一注册号请及时发送短信到伦理办公室，是伦理跟踪审查的必查项目。

单 位（章）：

主任委员（签名）：

2019年12月18日