ETHICAL APPROVALS

OF EACH STUDY CENTER

This trial was conducted in 14 study centers from the mainland of China. Guang'anmen Hospital is the leader center through all these 14 centers. Study protocol of this trial was approved by the institutional review board (IRB) of Guang'anmen Hospital, China Academy of Chinese Medical Sciences firstly, and then was approved by the ethics committees of all the other 13 centers.

密级：公开级

国家科技支撑计划课题任务书

项 目 编 号：	2012BAI24B00
项 目 名 称：	针灸疗效国际多中心临床评价研究
项目组织单位：	国家中医药管理局
课 题 编 号：	2012BAI24B01
课 题 名 称：	针灸治疗围绝经期综合征与功能性便秘等国际多中心随机对照临床试验
课题承担单位：	中国中医科学院广安门医院
课题起止日期：	2012 年 01 月 01 日至 2015 年 12 月 31 日
编 制 日 期：	2012 年 02 月 20 日

中华人民共和国科学技术部制

009 2012BAI24B01 2012030816242046

十、任务书签订各方签章

项目组织单位（甲方）：

负责人（签字）：

（公　章）

2012年 4月 12日

课题承担单位（乙方）：

课题承担单位法定代表人（签字）：

（公　章）

课题负责人（签字）

课题承担单位财务负责人（签字）：

2012年 2月 20日

科技部核准意见

科技部项目主管司：

负责人（签字）：

（公　章）

2012年 5月 8日

科技部科研条件与财务司：

负责人（签字）：

（公　章）

2012年 5月 8日

伦理审查批件

项目名称	电针和普芦卡必利治疗严重慢性便秘疗效比较-多中心随机对照试验		
批件号	2013EC124-01	项目来源	国家级课题
研究单位	中国中医科学院广安门医院，北京中医医院、陕西省中医院、东直门医院、浙江中医药大学附属三院、四川大学华西医院、湖南中医药大学第一附属医院、湖南中医药大学附属衡阳医院、山东中医药大学附属医院、江苏省中医院、广东省中医院、天津中医药大学第一附属医院、湖北省中医院、武汉市中西医结合医院		
申办者	无		
主要研究者	刘志顺	研究科室	针灸科
审查类别	复审	审查方式	快速审查
审查日期	2014-1-15	审查地点	中国中医科学院广安门医院
审查委员	谢利民，赵军		
批准文件及版本	研究方案（VERSION 2.0_20140102），知情同意书（VERSION 2.0_20140102），招募广告（VERSION 2.0_20140102），研究者手册（VERSION 1.0_20131118），筛选期排便日记卡（VERSION 1.0_20131115），随访期排便日记卡（VERSION 1.0_20131115），治疗期排便日记卡（VERSION 1.0_20131115）		
审查意见	根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》、国家药品食品监督管理局《药物临床试验质量管理规范》、《医疗器械临床试验规定》、《药物临床试验伦理审查工作指导原则》国家中医药管理局《中医药临床研究伦理审查管理规范》以及《赫尔辛基宣言》和国际医学科学组织委员会颁布的《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。 请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。 若在本批件有效期内未启动研究，本批件作废，需重新提交伦理审查申请。 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、招募材料等的任何修改，请申请人提交修正案审查申请。 如发生严重不良事件以及影响研究风险受益比的非预期不良事件，请申请人及时提交严重不良事件报告。 请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前1个月提交研究进展报告；申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。 研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，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 GCP 原则的情况，请申办者/监查员/研究者提交违背方案报告。 提前终止或完成临床研究，请及时提交结题报告。
有效期	2014 年 1 月 16 日～2015 年 1 月 15 日
联系人与联系电话	乔洁 010-88001552
主任委员签字	
中国中医科学院广安门医院伦理委员会（盖章）	
日期：2014 年 1 月 15 日	

Ethical Approval of Guang'anmen Hospital

Project Name	Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial		
Approval No.	2013EC124-01	**Project Sponsor**	the Twelfth Five-Year National Science and Technology Pillar Program (2012BAI24B01)
Study Centers	Guang'anmen Hospital, China Academy of Chinese Medical Sciences; Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University; Shaanxi Province Hospital of Traditional Chinese Medicine; Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine; The Third Affiliated Hospital of Zhejiang Chinese Medical University; West China Hospital of Sichuan University; The First Hospital of Hunan University of Chinese Medicine; Hengyang Hospital Affiliated to Hunan University of Chinese Medicine; The Affiliated Hospital of Shandong University of Traditional Chinese Medicine; Jiangsu Province Hospital of Traditional Chinese Medicine; Guangdong Province Hospital of Traditional Chinese Medicine; Hiser Medical Group; Hubei Provincial Hospital of Traditional Chinese Medicine; Wuhan Hospital of Traditional Chinese and Western Medicine		
Applicant (if any)	/		
Principal Investigator	Zhishun Liu	**Research Department**	Acupuncture Department
Review Category	Re-review	**Review Method**	Quick Review
Review Date	Jan 15th, 2014	**Review Location**	Guang'anmen Hospital, China Academy of Chinese Medical Sciences
Committee Members	Limin Xie, Jun Zhao		
Approved Files and Versions	Study Protocol (VERSION 2.0_20140102), Informed Consent (VERSION 2.0_20140102), Recruitment Poster (VERSION 2.0_20140102), Researcher Handbook (VERSION 1.0_20131118), Defecation Diary of Screening Period (VERSION 1.0_20131115), Defecation Diary of Treatment Period (VERSION 1.0_20131115), Defecation Diary of Follow-up Period (VERSION 1.0_20131115)		
Review Comments	According to "Ethical Review Methods for Biomedical Study Involving Human Subjects" issued by the Ministry of Health, "Good Clinical Practice", "Provisions for Clinical Trials of Medical Device" and "Guidelines for Ethical Review Work of Drug Clinical Trials" issued by State Food and Drug Administration (SFDA) of the People's Republic of China, "Management Specifications for Ethical Review of TCM Clinical Studies" issued by State Administration of Traditional Chinese Medicine, "Declaration of Helsinki", and "International Ethical Guidelines for Biomedical Research Involving Human Subjects" issued by Council for		

	International Organizations of Medical Sciences, the study protocol, informed consent, and recruitment documents were approved by the institutional review board (IRB) of Guang'anmen Hospital, China Academy of Chinese Medical Sciences with comments as followed: 1) Please perform the study by following the principle of GCP and the approved protocol. Please protect the health and rights of participants. 2) This approval will be invalid if the study does not start within the validity date of this approval. 3) Application of the review amendment should be submitted if any change of the main investigators, study protocol, informed consent and recruitment documents are made. 4) Reports of serious adverse events should be submitted, if any serious adverse event occurs, or any unexpected adverse event, which would have an influence on the risk and benefit ratio, occurs. 5) Please do the continuing review according to the requested frequency stipulated by the ethics committee and submit the research progress report one month before the deadline. Applicant should do the summary of the research progress reports from each center. If any situation affecting the study progress or gaining the risk of participants occurs, a report should be submitted in time. 6) The applicant or investigators should submit the protocol deviation report if any of the following occurs: patients who do not meet the inclusion criteria or meet the exclusion criteria; patients complete the trial who meet the termination criteria; patients who are given the wrong treatment session or dose; patients who are given the drugs which are not allowed in the protocol; patients' right/health are affected negatively. 7) Final report should be submitted if the study terminates or completes beforehand.
Validity Date	From Jan 16th, 2014 to Jan 15th, 2015
Contact	Jie Qiao, +86 010 88001552
Director Signature	Haibo Yin
IRB of Guang'anmen Hospital of China Academy of Chinese Medical Sciences (Seal)	
Jan 15th, 2014	

北京中医药大学东直门医院医学伦理委员会

IRB of Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine

伦理审查批件

Approval Notice Template

受理序号：ECSL-BDY-2014-06　　批件号：ECPJ-BDY-2014-06

项目名称：电针和普芦卡必利治疗严重慢性便秘疗效比较-多中心随机对照试验

申办单位：北京中医药大学东直门医院　　主要研究者：赵吉平

项目类别：科研课题　　批文号/课题编号：2012BAI24B01

方案版本号：VERSION2.0_20140102　　方案批准日期：2014.01

知情同意书版本号：VERSION2.0_20140102　　知情同意书批准日期：2014.01

伦理审查方式：☑会议审查　☐快速审查

应到会 14 人，出席本次会议人员 11 人，回避 0 人，缺席 3 人

根据中华人民共和国国家食品药品监督管理局（CFDA）《药物临床试验伦理审查工作指导原则》（2010 年）、《药物临床试验质量管理规范》（2003）、《中药品种保护指导原则》（2009），世界医学会《赫尔辛基宣言》（2008），卫生部《涉及人的生物医学研究伦理审查办法》（2007），国家中医药管理局《中医药临床研究伦理审查管理规范》（2010）以及国际医学科学组织委员会《人体生物医学研究国际道德指南》（2002）的伦理原则，经本伦理委员会审查决定：	☐同意临床研究方案 ☐不同意临床研究方案 ☐终止临床研究方案 ☐暂停临床研究方案

审查意见：

同意临床试验

注：本批件自签发日期有效期四年，研究负责人必须严格使用经审查同意的知情同意书文本和研究方案。如伦理审查批件失效时不能完成所有的临床研究（包括统计分析），请在本批件失效前一个月，递交持续审查申请。如研究结束并在审查有效期内，请递交研究结题报告。研究中发生涉及受试者或其他人风险的任何预期或非预期的不良事件，应立刻报告本伦理委员会；任何研究方案、知情同意书的修改包括研究人员得变更，必须递交研究方案修改申请表，经伦理委员会审查获得批准后执行。

主任委员☐副主任委员☐委员　　时 间：2014年 1 月 25日

北京中医药大学东直门医院医学伦理委员会　　地 点：第一会议室

本项目持续审查频率：☐3个月　☐6个月　☑12个月　联系人：商建伟 （010）84013229

北京中医药大学东直门医院医学伦理委员会

IRB of Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine

会议签到表

Meeting attendance sheet

项目名称	电针和普芦卡必利治疗严重慢性便秘疗效比较-多中心随机对照试验		
会议时间	2014.1.24	会议地点	第一会议室

成员	性别	伦理委员会职务	专业背景	签名
叶永安	男	主任	中医内科学	
高　颖	女	副主任	中医内科学	
柳红芳	女	副主任	中西医结合	
田金洲	男	委员	管　理	
张永涛	男	委员	西医内科学	
杨博华	男	委员	中医外科学	
鲁卫星	男	委员	院外代表	
王蓬文	女	委员	药理学	
曹俊岭	男	委员	药剂科	
赵波	男	委员	法律代表	
贺海东	男	委员	医疗器械	
孟歌红	女	委员	群众代表	
陈信义	男	委员	中医内科学	
彭淑莲	女	委员	中医外科学	

医学伦理委员会专用章

Approval Notice Template

Acceptance No. ECSL-BDY-2014-06	**Approval No.** ECPJ-BDY-2014-06
Project Name: Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial	
Applicant: Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine	**Center PI:** Jiping Zhao
Project Attribute: Scientific Research	**Project No.** 2012BAI24B01
Protocol Version: VERSION 2.0_20140102	**Protocol Approval Date:** Jan, 2014
Informed Consent Version: VERSION 2.0_20140102	**Informed Consent Version Approval Date:** Jan, 2014
Review Method: ■ Conference Review	□ Quick Review

Attendance required: 14 , Actual attendance: 11 , Avoiding 0 , Absent 3 .

According to the "Guidelines for Ethical Review Work of Drug Clinical Trials", "Good Clinical Practice", and "Guiding Principles for the Protection of Traditional Chinese Medicine Varieties" issued by State Food and Drug Administration (SFDA) of the People's Republic of China, , "Declaration of Helsinki", "Ethical Review Methods for Biomedical Study Involving Human Subjects" issued by the Ministry of Health, "Management Specifications for Ethical Review of TCM Clinical Studies" issued by State Administration of Traditional Chinese Medicine, and "International Ethical Guidelines for Biomedical Research Involving Human Subjects" issued by Council for International Organizations of Medical Sciences, the study protocol and informed consent was reviewed as:

■ Approved
□ Disapproved
□ Terminated
□ Suspended

Review Comments:

APPROVED

Note: The validity of this approval is 4 years. Study should be performed abiding by the approved documents strictly. If the trial does not complete within the validity (including the statistical analysis), please submit a request for continued review one month before the deadline. If the trial completes beforehand, please submit a final report. If any expected or unexpected adverse event occurs, please submit a report to the committee. If any change to the protocol, informed consent, or investigator is made, an application of review amendment should be submitted to the committee and get approved.

□ Chairman ■ Associate Chairman Signature	**Date:** Jan 25th, 2014
IRB of Dongzhimen Hospital affiliated to Beijing University of Chinese Medicine	**Location:** Conference Room 1
Continuing Review Frequency □ 3 months □ 6 months ■ 12 months	**Contact:** Jianwei Shang, +86 010 84013229

Meeting Attendance Sheet

Project Name	Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial		
Conference Date	Jan 24th, 2014	**Conference Location**	Conference Room 1

Name	**Gender**	**Title**	**Major**	**Signature**
Yong'an Ye	Male	Chairman	Chinese Internal Medicine	Yong'an Ye
Ying Gao	Female	Associate Chairman	Chinese Internal Medicine	Ying Gao
Hongfang Liu	Female	Associate Chairman	Integrated Chinese and Western medicine	Hongfang Liu
Jinzhou Tian	Male	Committee member	Management	Jinzhou Tian
Yongtao Zhang	Male	Committee member	Internal Medicine	Yongtao Zhang
Bohua Yang	Male	Committee member	Surgery of Traditional Chinese Medicine	Bohua Yang
Weixing Lu	Male	Committee member	Representative outside the Hospital	Weixing Lu
Pengwen Wang	Female	Committee member	Pharmacology	Pengwen Wang
Junling Cao	Male	Committee member	Pharmacy Department	Junling Cao
Bo Zhao	Male	Committee member	Legal Representative	Bo Zhao
Haidong He	Male	Committee member	Medical Equipment	Haidong He
Gehong Meng	Female	Committee member	Masses Representative	Gehong Meng
Xinyi Chen	Male	Committee member	Chinses Internal Medicine	Xinyi Chen
Shulian Peng	Female	Committee member	Surgery of Traditional Chinese Medicine	Shulian Peng

四川大学华西医院临床试验与生物医学伦理专委会审查批件

2014年临床试验（上市）审（8）号

科室（专业）： 中西医结合科	研究负责人： 王成伟　主治医师
药品：琥珀酸普芦卡必利片	剂型：片剂 规格：2mg
药品是否已进入本院药库： 是□　否■	
药品临床研究名称：电针和普芦卡必利治疗严重慢性便秘疗效比较-多中心随机对照试验	
申办者（或基金资助者）：中国中医科学院广安门医院	
审查方式： ■会议审查　□快速审查	
审查会议地点：四川大学华西医院老八教413会议室	

评审意见：

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。

3.请严格按照临床规范和药品使用说明书实施电针和药物研究。

审查结果：■同意　□作必要修正后同意　□作必要修正后再审　□不同意　□终止或暂停

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（SFDA《药物临床试验质量管理规范》（2003）、《医疗器械临床试验规定》（2004）、WMA《赫尔辛基宣言》和CIOMS《人体生物医学研究国际道德指南》、卫生部《涉及人的生物医学研究伦理审查办法（试行）（2007）》），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。

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。

本批件有效期为一年，逾期未实施的，则自行废止。

单 位（章）：

主任委员（签名）：

日期：2014年4月10日

联系方式：成都市武侯区国学巷 37 号四川大学华西医院老八教 412，孙荣国/左泽锦/李娜　电话/传真：028-85422654

（附件见背面）

四川大学华西医院临床试验与生物医学伦理专委会会议参会委员名单

姓名	性别	专业	职称	工作单位	签字	日期
曾勇（主任委员）	男	肝胆胰外科	教授	四川大学华西医院		2014.4.8.
孙荣国	男	医学管理	教授	四川大学华西医院		2014.4.8.
毛兵	男	中西医结合科	教授	四川大学华西医院		2014.4.8.
刘晓雪	女	烧伤整形科	教授	四川大学华西医院		
张瑞明	女	中西医结合科	教授	四川大学华西医院		
郑鸿	男	肿瘤科	教授	四川大学华西医院		
兰礼吉	男	伦理学	教授	四川大学政治学院		2014.4.8
傅政勇	男	法律学	律师	中豪律师集团（四川）事务所		2014.4.8.
赵建芳	女	教育学	教师	成都市武侯计算机实验小学		2014.4.8

Ethical Approval

2014 Clinical Trial (listed) Review No 8

Department: Department of integrated traditional Chinese and western medicine	**Research Leader:** Chengwei Wang
Drug: Prucalopride Succinate	**Form:** Tablet **Size:** 2mg
Whether the drug enters the drug storage: Yes □ No ■	
Project Name: Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial	
Responsible Institute: Guang'anmen Hospital, China Academy of Chinese Medical Sciences	
Review Method: ■ Conference Review □ Quick Review	
Conference Location: Conference Room 413, Old Teaching Building 8, West China Hospital of Sichuan University	

Review Comments:

1. The qualification of investigators met the ethical requirements.
2. The study protocol and informed consent met the ethical requirements.
3. Please perform the study of electro-acupuncture and prucalopride according to Good Clinic Practice and the drug instruction.

Review Conclusion:

■ Approved □ Approved after Revision □ Re-review after Revision □ Not Approved □ Terminated/Suspended

Continuing Review Frequency:

□ 3 months □ 6 months ■ 1 year □ NA

Please comply the relevant laws, regulations and rules ["Good Clinical Practice (2003)" and "Provisions for Clinical Trials of Medical Device (2004)" issued by State Food and Drug Administration (SFDA), "Declaration of Helsinki" issued by World Medical Association (WMA), "International Ethical Guidelines for Biomedical Research Involving Human Subjects" issued by Council for International Organizations of Medical Sciences, "Ethical Review Methods for Biomedical Study Involving Human Subjects (2007)" issued by the Ministry of Health].

Please perform the study by following the approved protocol. Please protect the health and rights of participants.

Application of the review amendment should be submitted if any change of main investigators, study protocol, informed consent, etc. are made.

If any serious adverse event (SAE) occurs, the applicant should submit a SAE emergency report, and then a detailed follow-up report.

Please submit the annual or termly review report. If any situation affecting the study progress or gaining the risk of participants occurred, a report should be submitted in time.

The applicant or investigators should submit the protocol deviation report if any of the following occurred: patients who did not meet the inclusion criteria or met the exclusion criteria; patients completed the trial who met the termination criteria; patients who were given the wrong treatment session or dose; patients who were given the medicine which was not allowed in the protocol; patients' right/health were affected negatively.

The applicants or investigators should submit the suspension/termination report if the study is suspended or terminated beforehand. Final report should be submitted if the study completes beforehand.

This approval will be invalid if the study does not start within the 1-year validity of this approval.

Institute (Seal):

Chairman (Signature):

Date: Apr 10th, 2014

Address: Conference Room 413, Old Teaching Building 8, West China Hospital of Sichuan University; 37 Guoxue Xiang, Wuhou District, Chengdu.

Contact: Guorong Sun, Zejin Zuo, Na Li; Tel +86 028 85422654

Committee's Members

Name	Gender	Major	Title	Institution	Signature	Date
Yong Zeng (Chairnan)	Male	Hepatopancreatobiliary Surgery	Professor	West China Hospital of Sichuan University	Yong Zeng	April 8th, 2014
Rongguo Sun	Male	Medical Management	Professor	West China Hospital of Sichuan University	Rongguo Sun	April 8th, 2014
Bing Mao	Male	Integrated Chinese and Western Medicine	Professor	West China Hospital of Sichuan University	Bing Mao	April 8th, 2014
Xiaoxue Liu	Female	Burn and Plastic Surgery	Professor	West China Hospital of Sichuan University		
Ruiming Zhang	Female	Integrated Chinese and Western Medicine	Professor	West China Hospital of Sichuan University		
Hong Zheng	Male	Oncology	Professor	West China Hospital of Sichuan University		
Liji Lan	Male	Ethics	Professor	Politics College of Sichuan University	Liji Lan	April 8th, 2014
Zhengyong Fu	Male	Law	Lawyer	Zhonghao Law Firm	Zhengyong Fu	April 8th, 2014
Jianfang Zhao	Female	Education	Teacher	Chengdu Wuhou Computer Experimental Primary School	Jianfang Zhao	April 8th, 2014

浙江中醫藥大學附屬第三醫院

临床试验伦理委员会审批件

试验项目名称	电针和普芦卡必利治疗严重慢性便秘疗效比较—多中心随机对照试验				
研究期限	2013-07-01 至 2015-6-30			试验类别	临床试验
受试者总例数	602	申请医疗机构承担	40	其他机构承担	562
试验目的	观察电针和普芦卡必利对严重慢性便秘患者的疗效				
监督管理部门	国家中医药管理局			项目编号	2012BAI24B01
申办单位	浙江中医药大学附属第三医院			主要负责人	姚新苗
医疗机构	浙江中医药大学附属第三医院			临床研究部门	针灸科
项目负责人	方剑乔			职称	主任中医师，教授
批件文号	ZSLL-KY-2014-001			批件有效期	2014.3-2015.07

	审查文件名称	版本	日期
√	伦理审查申请表	1.0	2014.1
√	临床研究方案概要	1.0	2014.1
√	知情同意书	1.0	2014.1
√	临床研究病例报告表	1.0	2014.1
√	研究人员信息表	1.0	2014.1

审批意见：

该项目设计科学，研究方法符合人体临床试验伦理学要求，同意进行临床试验研究。

浙江中医药大学附属第三医院
医学伦理委员会（盖章）
2014 年 01 月 27 日

伦理委员会联系电话：0571-88393504
联系地址：浙江省杭州市莫干山路 219 号 （310005）

The Third Affiliated Hospital of Zhejiang Chinese Medical University

Ethical Approval from the Clinical trials Ethics Committee

Project Name	Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial				
Study Period	Jul 01, 2013 to Jun 30, 2015			**Project Attribute**	Clinical Trial
No. of Participants	602	**No. Undertaking**	40	**No. Undertaking by Other Sites**	562
Objective	Evaluating if the efficacy of EA is non-inferior to that of prucalopride				
Supervision and Management Department	National Administration of Traditional Chinese Medicine			**Project No.**	2012BAI24B01
Applicant	The Third Affiliated Hospital of Zhejiang Chinese Medical University			**Major Responsible Person**	Xinmiao Yao
Medical Institute	The Third Affiliated Hospital of Zhejiang Chinese Medical University			**Research Department**	Acupuncture Department
Center PI	Jianqiao Fang			**Title**	Chief Physician, Professor
Approval No.	ZSLL-KY-2014-001			**Validity Date**	Mar 2014 to Jul 2015

Approval Documents		**Version**	**Date**
√	Ethical Review Application Form	1.0	Jan, 2014
√	Study Protocol Summary	1.0	Jan, 2014
√	Informed Consent	1.0	Jan, 2014
√	Case Report Form	1.0	Jan, 2014
√	Researcher Information Sheet	1.0	Jan, 2014

Review Comments:

The project is designed scientifically with the study method according to the requirement of the Human Research Subject Ethics Committee. The files submitted were approved.

The Third Affiliated Hospital of Zhejiang Chinese Medical University

Medical Ethics Committee (Seal)

Jan 27, 2014

Contact of Ethics Committee: +86 0571-88393504
Address: 219 Moganshan Road, Hangzhou, Zhejiang 310005

伦理审查批件

项目名称	电针和普卢卡比利治疗严重慢性便秘疗效比较—多中心随机对照试验		
项目编号	2012BAI24B01	项目来源	“十二五”国家科技支撑计划
牵头单位	湖南中医药大学附属衡阳医院		
中办者（如有）			
主要研究者	岳增辉		
审查类别	初始审查	审查方式	快速审查
审查日期	2014.01.06	审查地点	医院门诊楼 9 楼会议室
审查委员	王诚喜、龙双才、邹岳萍、徐基平、钟新林、匡肇、董秋萍		
批准文件	研究方案：（版本号：VERSION 2.0_20140102） 知情同意书[版本号：VERSION 2.0_20140102）		
审查意见	根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》、国家药品食品监督管理局《药物临床试验质量管理规范》、《医疗器械临床试验规定》、《药物临床试验伦理审查工作指导原则》、国家中医药管理局《中医药临床研究伦理审查管理规范》以及《赫尔辛基宣言》和国际医学科学组织委员会颁布的《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。 请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。 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、招募材料等的任何修改，请申请人提交修正案审查申请。 如发生严重不良事件以及影响研究风险受益比的非预期不良事件，请申请人及时提交严重不良事件报告。 请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申报者应当向组长单位伦理委员会提交各中心的研究进展的汇总报告；当出现任何可能显著影响试验进行或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。 研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，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 GCP 原则的情况，请中办者/监察员/研究者提交违背方案报告。 提前终止或完成临床研究，请及时提交结题报告。		
有效期	2014 年 3 月 1 日~2015 年 9 月 30 日		
联系人及电话	谢军，0734-8137737		
主任委员签字			
湖南中医药大学附属衡阳医院伦理委员会（盖章） 2014 年 1 月 6 日			

Ethical Approval

Project Name	Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial		
Project No.	2012BAI24B01	**Project Sponsor**	the Twelfth Five-Year National Science and Technology Pillar Program (2012BAI24B01)
Applicant	Hengyang Hospital Affiliated to Hunan University of Chinese Medicine		
Center PI	Zenghui Yue	**Review Method**	Quick Review
Review Date	Jan 6th, 2014	**Review Location**	Conference Room 9, Outpatient Building
Committee Members	Chengxi Wang, Shuangcai Long, Yueping Zou, Jiping Xu, Xinlin Zhong, Zhao Kuang, Qiuping Dong		
Approved Files and Versions	Study Protocol (VERSION 2.0_20140102), Informed Consent (VERSION 2.0_20140102)		
Review Comments	According to "Ethical Review Methods for Biomedical Study Involving Human Subjects" issued by the Ministry of Health, "Good Clinical Practice", "Provisions for Clinical Trials of Medical Device" and "Guidelines for Ethical Review Work of Drug Clinical Trials" issued by State Food and Drug Administration (SFDA) of the People's Republic of China, "Management Specifications for Ethical Review of TCM Clinical Studies" issued by State Administration of Traditional Chinese Medicine, "Declaration of Helsinki", and "International Ethical Guidelines for Biomedical Research Involving Human Subjects" issued by Council for International Organizations of Medical Sciences, the study protocol, informed consent, and recruitment documents were approved by the institutional review board (IRB) of Guang'anmen Hospital, China Academy of Chinese Medical Sciences with comments as followed: 1) Please perform the study by following the principle of GCP and the approved protocol. Please protect the health and rights of participants. 2) Application of the review amendment should be submitted if any change of the main investigators, study protocol, informed consent or recruitment documents are made. 3) Reports of serious adverse events should be submitted, if any serious adverse event occurs, or any unexpected adverse event, which would have an influence on the risk and benefit ratio, occurs. 4) Please do the continuing review according to the requested frequency stipulated by the ethics committee and submit the research progress report one month before the deadline. Applicant should do the summary of the research progress reports from each center. If any situation affecting the study progress or gaining the risk of participants occurs, a report should be submitted in time.		

	5) The applicant or investigators should submit the protocol deviation report if any of the following occurs: patients who do not meet the inclusion criteria or meet the exclusion criteria; patients complete the trial who meet the termination criteria; patients who are given the wrong treatment session or dose; patients who are given the grus which are not allowed in the protocol; patients' right/health are affected negatively. 6) Final report should be submitted if the study terminates or completes beforehand.
Validity Date	From Mar 1st, 2014 to Sep 30th, 2015
Contact	Jun Xie, 0734-8137737
Director Signature	
Ethics Committee of Hengyang Hospital Affiliated to Hunan University of Chinese Medicine (Seal)	
Jan 6th, 2014	

首都医科大学附属北京中医医院医学伦理委员会

伦理审查批件

审批号： 2014BL-034-02

项目名称	电针和普芦卡必利治疗严重慢性便秘疗效比较		
项目来源	“十二五”国家科技支撑计划项目		
申办单位	无		
CRO	无		
临床研究负责单位	中国中医科学院广安门医院		
临床研究参加单位	北京中医医院、北京中医药大学东直门医院、 四川大学华西医院、浙江中医药大学附属第三医院、湖南中医药大学附属衡阳医院、山东中医药大学附属医院、湖南中医药大学第一附属医院、湖北省中医院、江苏省中医院、陕西省中医院、天津中医药大学第一附属医院、广东省中医院武汉市中西医结合医院		
主要研究者	王麟鹏		
审查类别	复审审查	审查方式	快速审查
审查日期	2014 年 4 月 14 日		
审查地点	首都医科大学附属北京中医医院		
审查文件	修正的研究方案版本号：VERSION 3.0_20140414，版本日期：2014/04/14 修正的知情同意书：版本号：VERSION 3.0_20140414，版本日期：2014/04/14		
审查结果	同意 0 票	不同意 0 票	做必要的修正后同意 1 票
	做必要的修正后重审 0 票		终止或暂停试验 0 票

审查意见

根据卫生部《涉及人的生物医学研究伦理审查办法》(2007)，国家中医药管理局《中医药临床研究伦理审查管理规范》(2010)，SFDA《药物临床试验伦理审查工作指导原则》(2010)、《药物临床试验质量管理规范》(2003)、《中药品种保护指导原则》(2009)、《医疗器械临床试验规定》(2004)，以及 WMA《赫尔辛基宣言》(2008) 和 CIOMS《人体生物医学研究国际伦理指南》(2002) 的伦理原则，经本医学伦理委员会审查，同意按照所批准的临床研究方案、知情同意书、招募材料等开展本项试验/研究。

请遵循 GCP 规定和本伦理委员会批准的方案开展临床研究。

该项目进行中如发生下列情况，须及时书面报告本伦理委员会：

1） 对临床方案、知情同意书等的任何修改；

2） 更换主要研究者；

3） 发生严重不良事件；

4） 出现任何可能显著影响试验进行或增加受试者危险的情况；

5） 出现违反方案情况；

6） 暂停或提前终止临床研究。

本伦理委员会将对该项目跟踪审查，请申请人/申办方按照伦理委员会规定的年度或定期跟踪审查频率，在截止日期前 1 个月提交研究进展报告。

该项目完成后，请向本伦理委员会提交结题报告。

如该项目在批件有限期内未能启动临床研究，本批件作废，需要重新提交伦理审查申请。

年度/定期跟踪审查频率	1 年，请于 2015 年 4 月 15 日前 1 个月提交研究进展报告。
批件有效期	2015 年 4 月 15 日
联系人与联系电话	张会娜 010-52176565
伦理委员会主任签字	

首都医科大学附属北京中医医院
医学伦理委员会（盖章）

日期：2014 年 4 月 15 日

Ethical Approval

Approval No. 2014BL-034-02

Project Name	Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial		
Project Sponsor	the Twelfth Five-Year National Science and Technology Pillar Program (2012BAI24B01)		
Applicant	/		
CRO	/		
Participating Centers	Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University; Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine; West China Hospital of Sichuan University; The Third Affiliated Hospital of Zhejiang Chinese Medical University; Hengyang Hospital Affiliated to Hunan University of Chinese Medicine; The Affiliated Hospital of Shandong University of Traditional Chinese Medicine; The First Hospital of Hunan University of Chinese Medicine; Hubei Provincial Hospital of Traditional Chinese Medicine; Jiangsu Province Hospital of Traditional Chinese Medicine; Shaanxi Province Hospital of Traditional Chinese Medicine; Hiser Medical Group; Guangdong Province Hospital of Traditional Chinese Medicine; Wuhan Hospital of Traditional Chinese and Western Medicine		
Center PI	Linpeng Wang		
Review Category	Re-review	**Review Method**	Quick Review
Review Date	Apr 14th, 2014		
Review Location	Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University		
Approved Files and Versions	Revised Study Protocol: VERSION 3.0_20140414, Version Date: Apr 14, 2014 Revised Informed Consent: VERSION 3.0_20140414, Version Date: Apr 14, 2014		
Review Result	Approved: 0	Disapproved: 0	Approved after Necessary Revision: 1
	Re-review after Necessary Revision: 0		Termination or Suspension: 0

Review Comments

According to “Ethical Review Methods for Biomedical Study Involving Human Subjects (2007)” issued by the Ministry of Health, “Management Specifications for Ethical Review of TCM Clinical Studies (2010)” issued by State Administration of Traditional Chinese Medicine, “Guidelines for Ethical Review Work of Drug Clinical Trials (2010)”, “Good Clinical Practice (2003)”, “Guiding Principles for the Protection of Traditional Chinese Medicine Varieties (2009)”, and “Provisions for Clinical Trials of Medical Device (2004)” issued by State Food and Drug Administration (SFDA) of the People’s Republic of China, “Declaration of Helsinki (2008)”, and “International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002)” issued by Council for International Organizations of Medical Sciences, the study protocol, informed consent, and recruitment

documents were approved by the institutional review board (IRB) of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University with comments as followed:

Please perform the study by following the principle of GCP and the approved protocol.

Written report should be submitted to the ethics committee if any of the following happens:

1) Any amendment in study protocol, informed consent, recruitment documents;
2) Change of the main investigator;
3) Occurrence of severe adverse;
4) If any situation affecting the study progress or gaining the risk of participants occurred；
5) Protocol deviation;
6) The study is suspended or terminated beforehand.

Please do the continuing review according to the requested frequency stipulated by the ethics committee and submit the research progress report one month before the deadline.

Final report should be submitted after the completion of the study.

A new ethics approval application should be submitted if the study was not started within the validity date.

Review Frequency	1 Year, the research progress report should be submitted before Apr 15th, 2015
Validity Date	Apr 15th, 2015
Contact	Huina Zhang, +86 010 52176565
Director Signature	

Ethics Committee

Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University (Seal)

Apr 15th, 2014

伦理审查批件

Ethical Review Confirmation

批件号	（2014）伦审第（020）号--KY		
项目名称	电针和普芦卡必利治疗严重慢性便秘疗效比较—多中心随机对照试验		
项目来源	国家十二五科技支撑计划项目（编号：2012BAI24B01）		
研究单位	山东中医药大学附属医院		
研究负责人	杨佃会		
审查类别	修正案审查	审查方式	快速审查
审查日期	2014 年 4 月 28 日	审查地点	山东中医药大学附属医院东院图书馆楼 3 楼会议室
审查委员	陈柏楠、王东梅		
批准文件	国家十二五科技支撑计划项目任务书（编号：2012BAI24B01）		
审查文件	☑修正案审查申请　☑修正的知情同意书和招募材料☑其他伦理委员会或管理机构对申请项目的重要决定		

审查意见

根据卫生部《涉及人的生物医学研究伦理审查办法（试行（2007））》、SFDA《药物临床试验质量管理规范（2003）》、《医疗器械临床试验规定（2004）》、WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书开展本项研究。

请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。

研究开始前，请申请人完成临床试验注册。

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、招募材料等的任何修改，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。

请按照伦理委员会规定的年度/定期跟踪查频率，申请人在截止日期前 1 个月提交研究进展报告；当出现任何可能显著影响试验进行或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。

研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，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 GCP 原则的情况，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研究，请及时提交暂停/终止研究报告。

完成临床研究，请申请人提交结题报告。

年度/定期跟踪审查频率	12 个月
有效期	2014 年 4 月 28 日--2015 年 4 月 28 日
联系人与联系电话	张倩　0531-68616648
主任委员签字	
伦理委员会	（盖章）
日期	2014 年 4 月 28 日

Ethical Approval

Approval No.	（2014）Ethical Review No (020)--KY		
Project Name	Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial		
Project Sponsor	the Twelfth Five-Year National Science and Technology Pillar Program (2012BAI24B01)		
Study Centers	The Affiliated Hospital of Shandong University of Traditional Chinese Medicine		
Center PI	Dianhui Yang		
Review Category	Re-review	**Review Method**	Quick Review
Review Date	Apr 28th, 2014	**Review Location**	Conference room, the 3rd Floor of the Library, East Wing of the Affiliated Hospital of Shandong University of TCM
Committee Members	Bonan Chen, Dongmei Wang		
Approved File	Study Protocol (Project No. 2012BAI24B01)		
Review Files	■ Application of Re-review ■ Revised informed consent and recruiting documents ■ Important decisions of the application from other ethics committees or management institution		
Review Comments	According to 'Ethical Review Methods for Biomedical Study Involving Human Subjects (2007)' issued by the Ministry of Health, 'Good Clinical Practice (2003)' and 'Provisions for Clinical Trials of Medical Device (2004)' issued by State Food and Drug Administration (SFDA) of the People's Republic of China, 'Declaration of Helsinki (2008)', and 'International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002)' issued by Council for International Organizations of Medical Sciences, the study protocol and informed consent were approved by the ethics committee with comments as followed: 1) Please perform the study by following the principle of GCP and the approved protocol. Please protect the health and rights of participants. 2) Applicants are requested to complete the clinical trial registration before the start of the study. 3) Application of the review amendment should be submitted if any change of the main investigators, study protocol, informed consent or recruitment documents is made. 4) Reports of serious adverse events should be submitted, if any serious adverse event occurs. 5) Please do the continuing review according to the requested frequency stipulated by the ethics committee and submit the		

	research progress report one month before the deadline. If any situation affecting the study progress or gaining the risk of participants occurs, a report should be submitted in time. 6) The applicant or investigators should submit the protocol deviation report if any of the following occurs: patients who do not meet the inclusion criteria or meet the exclusion criteria; patients complete the trial who meet the termination criteria; patients who are given the wrong treatment session or dose; patients who are given the drugs which are not allowed in the protocol; patients' right/health are affected negatively. 7) Suspend/Terminate report should be submitted if the applicant suspend/terminate the study beforehand. 8) The applicant should submit the final report after completing the study.
Review Frequency	12 months
Validity Date	From Apr 28th, 2014 to Apr 28th, 2015
Contact	Qian Zhang, +86 0531 68616648
Director Signature	
Ethics Committee of the Affiliated Hospital of Shandong University of TCM (Seal)	
Apr 28th, 2014	

编号：AF/SC-08/01.0

伦理审查批件

批件号	湖南中医药大学第一附属医院伦理委员会 HN-LL-KY-2014-001-01		
项目名称	电针和普芦卡必利治疗严重慢性便秘疗效比较-多中心随机对照试验		
项目来源	“十二五”国家科技支撑计划 2012BAI24B01		
研究单位	中国中医科学院广安门医院、四川大学华西医院、湖南中医药大学第一附属医院、天津中医药大学第一附属医院等		
主要研究者	章薇		
审查类别	初始审查	审查方式	快速审查
审查日期	2014.1.16	审查地点	医院会议室
审查委员	郭志华、贺菊乔，赵艳玲，陈其华，黄孟君，张志国，张月娟，谭劲，钟　晓		
批准文件	临床研究方案（版本号:VERSION2.0-20140102） 知情同意书（版本号: VERSION2.0）		

审查意见

根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》（2007）、SFDA《药物临床试验质量管理规范（2003）》、《医疗器械临床试验规定（2004）》、WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。

请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。

研究开始前，请申请人完成临床试验注册。

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、招募材料等的任何修改，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。

请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行、或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。

研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，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 GCP 原则的情况，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研究，请及时提交暂停/终止研究报告。

完成临床研究，请申请人提交结题报告。	
年度/定期跟踪审查频率	24 个月
有效期	自批件下发之日起一年内有效
联系人与联系电话	王华　赵鸿　0731-85369233
主任委员签字	
伦理委员会	湖南中医药大学第一附属医院伦理委员会　（盖章）
日期	2014 年 1 月 17 日

Ethics Approval

Approval No.	HN-LL-KY-2014-001-01 The ethics committee of the First Hospital of Hunan University of Chinese Medicine		
Project Name	Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial		
Project Sponsor	the Twelfth Five-Year National Science and Technology Pillar Program (2012BAI24B01)		
Study Centers	Guang'anmen Hospital, China Academy of Chinese Medical Sciences; Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University; Shaanxi Province Hospital of Traditional Chinese Medicine; Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine; The Third Affiliated Hospital of Zhejiang Chinese Medical University; West China Hospital of Sichuan University; The First Hospital of Hunan University of Chinese Medicine; Hengyang Hospital Affiliated to Hunan University of Chinese Medicine; The Affiliated Hospital of Shandong University of Traditional Chinese Medicine; Jiangsu Province Hospital of Traditional Chinese Medicine; Guangdong Province Hospital of Traditional Chinese Medicine; Hiser Medical Group; Hubei Provincial Hospital of Traditional Chinese Medicine; Wuhan Hospital of Traditional Chinese and Western Medicine		
Center PI	Wei Zhang		
Review Category	Initial review	**Review Method**	Quick Review
Review Date	Jan 16th, 2014	**Review Location**	Conference Room of the Hospital
Committee Members	Zhihua Guo, Juqiao He, Yanling Zhao, Qihua Chen, Mengjun Huang, Zhiguo Zhang, Yuejuan Zhang, Jin Tan, Xiao Zhong		
Approved Files	Study Protocol (VERSION2.0-20140102), Informed Consent (VERSION 2.0)		

Review Comments

According to 'Ethical Review Methods for Biomedical Study Involving Human Subjects (2007)' issued by the Ministry of Health, 'Good Clinical Practice (2003)' and 'Provisions for Clinical Trials of Medical Device (2004)' issued by State Food and Drug Administration (SFDA) of the People's Republic of China, 'Declaration of Helsinki (2008)', and 'International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002)' issued by Council for International Organizations of Medical Sciences, the study protocol and informed consent were approved by the ethics committee with comments as followed:

1) Please perform the study by following the principle of GCP and the approved protocol. Please protect the health and rights of participants.
2) Applicants are requested to complete the clinical trial registration before the start of the study.
3) Application of the review amendment should be submitted if any change of the main investigators, study protocol, informed consent or recruitment documents is made.
4) Reports of serious adverse events should be submitted, if any serious adverse event occurs.

5) Please do the continuing review according to the requested frequency stipulated by the ethics committee and submit the research progress report one month before the deadline. Applicant should do the summary of the research progress reports from each center. If any situation affecting the study progress or gaining the risk of participants occurs, a report should be submitted in time. 6) The applicant or investigators should submit the protocol deviation report if any of the following occurs: patients who do not meet the inclusion criteria or meet the exclusion criteria; patients complete the trial who meet the termination criteria; patients who are given the wrong treatment session or dose; patients who are given the grus which are not allowed in the protocol; patients' right/health are affected negatively. 7) Suspend/Terminate report should be submitted if the applicant suspend/terminate the study beforehand. 8) The applicant should submit the final report after completing the study	
Review Frequency	24 months
Validity Date	Within one year since the approval date
Contact	Hua Wang and Hong Zhao +86 0731 85369233
Director Signature	
Ethics Committee of The First Hospital of Hunan University of Chinese Medicine (Seal)	
Jan 17th, 2014	

湖北省中医院伦理委员会

Ethics Committee of Hubei Province Hospital of Traditional Chinese Medicine

伦理审查批件

Ethics Review Approval

批件号	HBZY2014-C005-01		
项目名称	电针和普芦卡必利治疗严重慢性便秘疗效比较—多中心随机对照试验		
申办者	“十二五”国家科技支撑计划		
研究单位	中国中医科学院广安门医院 北京中医药大学东直门医院 四川大学华西医院 湖南中医药大学附属衡阳医院 湖南中医药大学第一附属医院 湖北省中医院 江苏省中医院 陕西省中医院 天津中医药大学第一附属医院 青岛海慈医疗集团		
主要研究者	周仲瑜 主任医师		
审查类别	初始审查、复审	审查方式	会议审查、快速审查
审查日期	2014-02-26、03-10	审查地点	湖北省中医院伦理办会议室
审查委员	涂远超、刘建忠、郭艳红、费兰波、程业刚、王小琴、高文喜、周忠明、胡晓雪、石艳红、吴胜利		
批准文件	临床试验方案版本号/日期：VERSION 2.0_20140102/2014-01-02； 知情同意书版本号/日期：VERSION 2.1_20140226/2014-02-26。		

审查意见

根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》（2007）、SFDA《药物临床试验质量管理规范（2003）》、《医疗器械临床试验规定（2004）》、WMA《赫尔辛基宣言》和CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书开展该项研究。

请遵循GCP原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。研究开始前，请申请人完成临床试验注册。

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、招募材料等的任何修改，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。

请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前1个月提交研究进展报告。

出现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GCP原则的情况，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研究，请及时提交暂停/终止研究报告。

完成临床研究，请申请人提交结题报告。

跟踪审查频率	12个月
有效期	12个月
联系人与联系电话	张馨、陈学军 027-88920956
主任委员签字	涂远超

湖北省中医院伦理委员会（盖章）

日期：2014年03月12日

Ethics Committee of Hubei Province Hospital of Traditional Chinese Medicine

Ethics Review Approval

Approval No.	HBZY2014-C005-01		
Project Name	Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial		
Project Sponsor	the Twelfth Five-Year National Science and Technology Pillar Program (2012BAI24B01)		
Study Centers	Guang'anmen Hospital, China Academy of Chinese Medical Sciences; Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University; Shaanxi Province Hospital of Traditional Chinese Medicine; Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine; The Third Affiliated Hospital of Zhejiang Chinese Medical University; West China Hospital of Sichuan University; The First Hospital of Hunan University of Chinese Medicine; Hengyang Hospital Affiliated to Hunan University of Chinese Medicine; The Affiliated Hospital of Shandong University of Traditional Chinese Medicine; Jiangsu Province Hospital of Traditional Chinese Medicine; Guangdong Province Hospital of Traditional Chinese Medicine; Hiser Medical Group; Hubei Provincial Hospital of Traditional Chinese Medicine; Wuhan Hospital of Traditional Chinese and Western Medicine		
Center PI	Zhongyu Zhou		
Review Category	Initial Review Re-review	**Review Method**	Conference Revies Quick Review
Review Date	Feb 26th, 2014 Mar 10th, 2014	**Review Location**	Conference room of the Ethics Committee, Hubei Province Hospital of Traditional Chinese Medicine
Committee Members	Yuanchao Tu, Jianzhong Liu, Yanhong Guo, Lanbo Fei, Yegang Cheng, Xiaoqin Wang, Wenxi Gao, Zhongming Zhou, Xiaoxue Hu, Yanhong Shi, Shengli Wu		
Approved File	Study Protocol, Version No./Date: VERSION 2.0_20140102/Jan 02, 2014 Informed Consent, Version No./Date: VERSION 2.1_20140226/Feb 26, 2014		

Review Comments

According to 'Ethical Review Methods for Biomedical Study Involving Human Subjects (2007)' issued by the Ministry of Health, 'Good Clinical Practice (2003)' and 'Provisions for Clinical Trials of Medical Device (2004)' issued by State Food and Drug Administration (SFDA) of the People's Republic of China, 'Declaration of Helsinki (2008)', and 'International Ethical Guidelines for Biomedical Research Involving Human Subjects (2002)' issued by Council for International Organizations of Medical Sciences, the study protocol and informed consent were approved by the ethics committee with comments as followed:

1) Please perform the study by following the principle of GCP and the approved protocol. Please protect the health and rights of participants.

2) Applicants are requested to complete the clinical trial registration before the start of the study.
3) Application of the review amendment should be submitted if any change of the following being made: main investigators, study protocol, informed consent, recruitment documents.
4) Please do the continuing review according to the requested frequency stipulated by the ethics committee and submit the research progress report one month before the deadline.
5) The applicant or investigators should submit the protocol deviation report if any of the following occurs: patients who do not meet the inclusion criteria or meet the exclusion criteria; patients complete the trial who meet the termination criteria; patients who are given the wrong treatment session or dose; patients who are given the drugs which are not allowed in the protocol; patients' right/health are affected negatively.
6) Suspend/Terminate report should be submitted if the applicant suspend/terminate the study beforehand.
7) The applicant should submit the final report after completing the study.

Review Frequency	12 months
Validity Date	12 months since the approval date
Contact	Xin Zhang and Xuejun Chen, +86 027 88920956
Director Signature	Yuanchao Tu

Ethics Committee of Hubei Province Hospital of Traditional Chinese Medicine (Seal)

Mar 12nd, 2014

伦理审查批件

批件号	2014NL-044-02		
项目名称	电针和普芦卡必利治疗严重慢性便秘疗效比较—多中心随机对照试验		
项目来源	“十二五”国家科技支撑计划		
研究单位	江苏省中医院，中国中医科学院广安门医院		
主要研究者	孙建华		
审查类别	复审申请	审查方式	快速审查
审查日期	2014 年 08 月 05 日	审查地点	
审查委员	房良华		
审查文件	修改的临床研究方案 版本号：VERSION 4.0 版本日期：2014-07-31 修改的知情同意书 版本号：VERSION 4.0 版本日期：2014-07-31 修改的招募材料 随访期排便日记卡，药物组受试者治疗情况、药物不良反应和不良事件记录表，筛选期排便日记卡，治疗期排便日记卡		

审查意见

根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》(2007)、SFDA《药物临床试验质量管理规范（2003）》、《医疗器械临床试验规定（2004）》、WMA《赫尔辛基宣言》和CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。

请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。研究开始前，请申请人完成临床试验注册。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、招募材料等的任何修改，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。请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行、或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，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 GCP 原则的情况，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研究，请及时提交暂停/终止研究报告。完成临床研究，请申请人提交结题报告。本项临床试验应当在批准之日起一年内实施，逾期未实施的，本批件自行废止。

年度/定期跟踪审查频率	请于 2015 年 08 月 05 日前 1 个月提交研究进展报告
有效期	12 个月
联系人与联系电话	吴静　025-86560515
主席签字	
伦理委员会	南京中医药大学附属医院（江苏省中医院）伦理委员会（盖章）
日期	2014 年 08 月 05 日

Ethics Review Approval

Approval No.	2014NL-044-02		
Project Name	Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial		
Project Sponsor	the Twelfth Five-Year National Science and Technology Pillar Program (2012BAI24B01)		
Cooperation Center	Jiangsu Province Hospital of Traditional Chinese Medicine		
Center PI	Jianhua Sun		
Review Category	Re-review	**Review Method**	Quick Review
Review Date	Aug 05th, 2014	**Review Location**	
Committee Members	Lianghua Fang		
Approved Files	Revised Study Protocol, Version: VERSION 4.0, Date: Jul 31, 2014 Revised Informed Consent, Version: VERSION 4.0, Date: Jul 31, 2014 Revised Recruitment Documents Defecation Diaries of the screening, treatment and follow-up period Forms of drug-related side effect and forms of the adverse events		

Review Comments

According to "Ethical Review Methods for Biomedical Study Involving Human Subjects" issued by the Ministry of Health, "Good Clinical Practice", "Provisions for Clinical Trials of Medical Device" and "Guidelines for Ethical Review Work of Drug Clinical Trials" issued by State Food and Drug Administration (SFDA) of the People's Republic of China, "Management Specifications for Ethical Review of TCM Clinical Studies" issued by State Administration of Traditional Chinese Medicine, "Declaration of Helsinki", and "International Ethical Guidelines for Biomedical Research Involving Human Subjects" issued by Council for International Organizations of Medical Sciences, the study protocol, informed consent, and recruitment documents were approved by the institutional review board (IRB) of Guang'anmen Hospital, China Academy of Chinese Medical Sciences with comments as followed:

Please perform the study by following the principle of GCP and the approved protocol. Please protect the health and rights of participants. Applicants are requested to complete the clinical trial registration before the start of the study. Application of the review amendment should be submitted if any change of the main investigators, study protocol, informed consent or recruitment documents is made. Emergency reports of serious adverse events should be submitted, if any serious adverse event occurs. A detailed follow-up report on serious adverse events should be submitted as soon as possible after the emergency report. Please do the continuing review according to the requested frequency stipulated by the ethics committee and submit the research progress report one month before the deadline. Applicant should do the summary of the research progress reports from each center. If any situation affecting the study progress or gaining the risk of participants occurs, a report should be submitted in time. The applicant or investigators should submit the protocol deviation report if any of the following occurs: patients who do not meet the inclusion criteria or meet the exclusion criteria; patients complete the trial who meet the termination criteria; patients who are given the wrong treatment session or dose; patients who are

given the drugs which are not allowed in the protocol; patients' right/health are affected negatively. Suspend/Terminate report should be submitted if the applicant suspend/terminate the study beforehand. The applicant should submit the final report after completing the study. This approval will be invalid if the study does not start within one year since the approval.	
Review Frequency	A report of the study progress should be submitted one month before Aug 05th, 2015
Validity Date	12 months
Contact	Jing Wu, +86 025 86560515
Director Signature	
Ethics Committee of Jiangsu Province Hospital of Traditional Chinese Medicine (Seal)	
Aug 05th, 2014	

陕西省中医医院伦理委员会

临床研究伦理审查批件

（2014）伦审第（03）号

项目名称	电针和普鲁卡必利治疗严重慢性便秘疗效比较：多中心随机对照试验				
申请单位	陕西省中医医院针灸科				
项目来源	国家科技支撑计划	项目编号：2012BAI24B00	课题编号：2012BAI24B01		
承担研究任务科室	针灸科	主要研究者	苏同生	职称	主任医师
会议时间	2014 年 03 月 14 日	会议地点	行政四楼小会议室	审查方式	会议审查
审查文件	1、临床研究方案（版本号及日期：VERSION1.0_20131115）； 2、病例报告表（版本号及日期：VERSION2.0_20140102 ）； 3、知情同意书（版本号及日期：VERSION2.0_20140102 ）； 4、研究者专业履历及专业科室人员配备、设备设施情况。				
审查内容	研究者的资格： 人员配备： 设备条件： 知情同意书： 获取知情同意书的方法： 研究方案： 受试者因参加临床试验发生不良反应或意外：	符合要求■ 符合要求■ 符合要求■ 符合要求■ 恰当■ 符合要求■ 有有效抢救措施■ 有补偿规定■	不符合要求□ 不符合要求□ 不符合要求□ 不符合要求□ 不恰当□ 不符合要求□ 无有效抢救措施□ 无补偿规定□		
审查意见	同意	作必要的修改后同意	作必要的修正后重审	不同意	终止或暂停已批准的研究
	8 人	0	0	0	0
出席人数	应到：9 人	实到：9 人	回避：1 人(投票时)	请假：0 人	
审批意见：经审查该项目符合 GCP、《赫尔辛基宣言》要求，同意开展临床研究。					
主任委员签字： 日期：2014 年 3 月 14 日		会议记录者签字： 日期：2014 年 3 月 14 日		联系电话：029-87251691	

Ethics Committee of Shaanxi Province Hospital of Traditional Chinese Medicine

Ethical Review Approval

(2014) Ethical Review No (03)

Project Name	Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial				
Applicant	Shaanxi Province Hospital of Traditional Chinese Medicine				
Project Sponsor	the Twelfth Five-Year National Science and Technology Pillar Program		**Project No.**	2012BAI24B01	
Research Department	Acupuncture Department	**Center PI**	Tongsheng Su	**Title**	Chief Physician
Review Date	Mar 14, 2014	**Location**	Conference Room, 4th Floor of the administration building	**Review Method**	Quick Review
Approved Files	1. Study Protocol (VERSION 1.0_20131115); 2. Case Report Form (VERSION 2.0_20140102); 3. Informed Consent (VERSION 2.0_20140102); 4. Professional Resume of the researchers and the personnel, facilities and equipment of Acupuncture Department				

Review Content			
Researcher Qualification	■ meet the requirement	□ Do not meet the requirement
Personnel	■ meet the requirement	□ Do not meet the requirement
Facilities and Equipment	■ meet the requirement	□ Do not meet the requirement
Informed Consent	■ meet the requirement	□ Do not meet the requirement
the way obtaining informed consent	■ Appropriate	□ inappropriate
Study protocol	■ meet the requirement	□ Do not meet the requirement
Participants	■ have effective rescue measure	□ Do not have effective rescue measure
if adverse events occur	■ meet the requirement	□ Do not meet the requirement

Review Result	Approved	Approved after Necessary Revision	Re-review after Necessary Revision	Disapproved	Termination or Suspension
	8	0	0	0	0
Attendance	Attendance required: 9	Actual attendance: 9	Avoiding: 1 (during voting)	Absent: 0	

Review Comments:

The files of this project were approved according to the requirements of Good Clinical Practice and Declaration of Helsinki

Signature of the Director **Date:** Mar 14, 2014	**Signature of Conference Recorder** **Date:** Mar 14, 2014	**Contact Phone No.** +86 029 87251691

编号 2014-1
注册 Z 项数 Z

伦理审查批件

项目名称	电针和普芦卡必利治疗严重慢性便秘疗效比较-多中心随机对照试验		
批件号	2014-1-Z	项目来源	国家级课题
研究单位	中国中医科学院广安门医院，北京中医医院，陕西省中医院，东直门医院，浙江中医药大学附属三院，四川大学华西医院，湖南中医药大学第一附属医院，湖南中医药大学附属衡阳医院，山东中医药大学附属医院，江苏省中医院，广东省中医院，青岛市海慈医疗集团，湖北省中医院，武汉市中西医结合医院		
申办者	无		
主要研究者	刘立安	研究科室	针灸科
审查类别	初审	审查方式	快速审查
审查日期	2014 年 2 月 27 日	审查地点	青岛市海慈医疗集团
审查委员	孙顺昌、武宝通、李界平		
批准文件及版本	研究方案（VERSION 2.0_20140102），知情同意书（VERSION 2.0_20140102），招募广告（VERSION 2.0_20140102），研究者手册（VERSION 1.0_20131118），筛选期排便日记卡（VERSION 1.0_20131115），随访期排便日记卡（VERSION 1.0_20131115），治疗期排便日记卡（VERSION 1.0_20131115），		
审查意见	根据卫生部《涉及人的生物医学研究伦理审查办法（试行）》、国家药品食品监督管理局《药物临床试验质量管理规范》、《医疗器械临床试验规定》、《药物临床试验伦理审查工作指导原则》、国家中医药管理局《中医药临床研究伦理审查管理规范》以及《赫尔辛基宣言》和国际医学科学组织委员会颁布的《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。 请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康和权利。 若在本批件有效期内未启动研究，本批件作废，需重新提交伦理审查申请。 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、招募材料等的任何修改，请申请人提交修正案审查申请。 如发生严重不良事件以及影响研究风险受益比的非预期不良事件，请申请人及时提交严重不良事件报告。 请按照伦理委员会规定的年度/定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告；中办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。 研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，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 GCP 原则的		

有效期	2014年1月18日～2015年1月17日
联系人与联系电话	
主任委员签字	
青岛市海慈医疗集团伦理委员会（盖章）	
日期： 2014 年 2 月 27 日	

Ethical Approval

Project Name	Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial		
Approval No.	2014-1-2	**Project Sponsor**	the Twelfth Five-Year National Science and Technology Pillar Program (2012BAI24B01)
Study Centers	Guang'anmen Hospital, China Academy of Chinese Medical Sciences; Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University; Shaanxi Province Hospital of Traditional Chinese Medicine; Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine; The Third Affiliated Hospital of Zhejiang Chinese Medical University; West China Hospital of Sichuan University; The First Hospital of Hunan University of Chinese Medicine; Hengyang Hospital Affiliated to Hunan University of Chinese Medicine; The Affiliated Hospital of Shandong University of Traditional Chinese Medicine; Jiangsu Province Hospital of Traditional Chinese Medicine; Guangdong Province Hospital of Traditional Chinese Medicine; Hiser Medical Group; Hubei Provincial Hospital of Traditional Chinese Medicine; Wuhan Hospital of Traditional Chinese and Western Medicine		
Applicant (if any)	/		
Principal Investigator	Li'an Liu	**Research Department**	Acupuncture Department
Review Category	Initial Review	**Review Method**	Quick Review
Review Date	Feb 27th, 2014	**Review Location**	Hiser Medical Group
Committee Members	Shunchang Sun, Baotong Wu, Jieping Li		
Approved Files and Versions	Study Protocol (VERSION 2.0_20140102), Informed Consent (VERSION 2.0_20140102), Recruitment Poster (VERSION 2.0_20140102), Researcher Handbook (VERSION 1.0_20131118), Defecation Diary of Screening Period (VERSION 1.0_20131115), Defecation Diary of Treatment Period (VERSION 1.0_20131115), Defecation Diary of Follow-up Period (VERSION 1.0_20131115)		
Review Comments	According to "Ethical Review Methods for Biomedical Study Involving Human Subjects" issued by the Ministry of Health, "Good Clinical Practice", "Provisions for Clinical Trials of Medical Device" and "Guidelines for Ethical Review Work of Drug Clinical Trials" issued by State Food and Drug Administration (SFDA) of the People's Republic of China, "Management Specifications for Ethical Review of TCM Clinical Studies" issued by State Administration of Traditional Chinese Medicine, "Declaration of Helsinki", and "International Ethical Guidelines for Biomedical Research Involving Human Subjects" issued by Council for International Organizations of Medical Sciences, the study protocol, informed consent, and recruitment documents were approved by the ethics committee of Hiser Medical Group with comments as followed:		

	1) Please perform the study by following the principle of GCP and the approved protocol. Please protect the health and rights of participants. 2) This approval will be invalid if the study does not start within the validity date of this approval. 3) Application of the review amendment should be submitted if any change of the main investigators, study protocol, informed consent or recruitment documents is made. 4) Reports of serious adverse events should be submitted, if any serious adverse event occurs, or any unexpected adverse event, which would have an influence on the risk and benefit ratio, occurs. 5) Please do the continuing review according to the requested frequency stipulated by the ethics committee and submit the research progress report one month before the deadline. Applicant should do the summary of the research progress reports from each center. If any situation affecting the study progress or gaining the risk of participants occurs, a report should be submitted in time. 6) The applicant or investigators should submit the protocol deviation report if any of the following occurs: patients who do not meet the inclusion criteria or meet the exclusion criteria; patients complete the trial who meet the termination criteria; patients who are given the wrong treatment session or dose; patients who are given the drugs which are not allowed in the protocol; patients' right/health are affected negatively. 7) Final report should be submitted if the study terminates or completes beforehand.
Validity Date	From Jan 18th, 2015 to Jan 17th, 2015
Contact	
Director Signature	
Ethics Committee of Hiser Medical Group (Seal)	
Feb 27th, 2014	

广东省中医院伦理委员会
Institutional Ethics Committee of Guangdong Provincial Hospital of Traditional Chinese Medicine
伦理审查批件
Approval Notice

批件号：广东省中医院伦理委员会 B2014-010-02

审查会议日期	2014 年 05 月 09 日
审查会议地点	广东省广州市大德路 111 号广东省中医院东区 12 楼会议室
临床研究批文	国家“十二五”针灸疗效国际多中心临床评价研究项目编号：2012BAI24B01
临床研究项目	针灸疗效国际多中心临床评价研究-电针和普芦卡必利治疗严重慢性便秘疗效比较—多中心随机对照试验
审查文件	1. 伦理审查申请表 2. 项目技术合作合同 3. 病例筛选表 4. 工作手册（版本号：VERSION 2.0_20140102） 5. 课题负责人履历 6. 招募受试者材料 7. 知情同意书 8. 电针安全性和接受性评价表；受试者治疗情况、安全性评价和不良事件记录表 9. 病例报告表、排便日记卡 10. 研究方案（版本号：VERSION 2.0_20140102） 11. 药品说明书
申办者	中国中医科学院广安门医院
临床研究单位	广东省中医院大针灸科
主要研究者	符文彬 教授
伦理审查方式	会议审查
参会委员	曾星、丘小惠、许树柴、刘旭生、邓丽丽、李立凯、李泳、余谊君
审查意见	根据中华人民共和国国家药品食品监督管理局 2003 年颁布实施的《药物临床试验质量管理规范》、卫生部 2007 年颁布的《涉及人的生物医学研究伦理审查办法》，《赫尔辛基宣言》、国际医学科学组织委员会颁布的《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按照上述临床研究方案和上述已通过审查的文件进行 针灸疗效国际多中心临床评价研究-电针和普芦卡必利治疗严重慢性便秘疗效比较—多中心随机对照试验 项目的临床研究。
伦理委员会声明	本批件将在各中心机构及其伦理委员会备案。如果对方案在本机构的可行性（包括研究者的资格与经验、设备与条件等）有不同意见，请及时与本伦理委员会联系。 如项目暂停/提前终止/完成临床研究，请及时通知伦理委员会。如发生严重不良事件以及影响研究风险受益比的非预期不良事件，应及时报告本伦理委员会。如临床研究方案、知情同意书的任何修改，主要研究者更换，应及时通知伦理委员会，重新审查，获得批准后执行。发现影响受试者参加研究意愿的违反方案情况应及时报告，同时，请在本批件失效日期前 1 个月提交研究进度/结题报告，以便对该项目进行跟踪审查。
批件有效期	自 2014 年 05 月 09 日起 至 2016 年 05 月 09 日止
跟踪审查频率	半年
预计审查日期	2014 年 11 月 09 日
联系电话	020-81887233 转 30818，联系人：盖娟娟
主任委员签字	符文彬
	广东省中医院伦理委员会（盖章） 日期：2014 年 05 月 09 日

Institutional Ethics Committee of Guangdong Province Hospital of Traditional Chinese Medicine

Ethical Approval

Approval No. B2014-010-02

Review Date	May 09, 2014
Location	Conference Room 12, The Eastern Wing of Guangdong Province Hospital of Traditional Chinese Medicine 111 Dade Road, Guangzhou, Guangdong
Project Sponsor	the Twelfth Five-Year National Science and Technology Pillar Program (2012BAI24B01)
Project Name	Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial
Approved Files	1. Ethic Review Application Form; 2. Technical Service Contract; 3. Case Screening Form; 4. Researcher Handbook (VERSION 2.0_20140102) 5. Resume of the Center PI; 6. Recruiting Documents; 7. Informed Consent; 8. Evaluating Form for the Acceptability and Safety of Electro-acupuncture; Form for the adverse events; 9. Case Report Form, Defecation Diaries; 10. Study Protocol (VERSION 2.0_20140102); 11. Drug Instruction
Leading Center	Guang'anmen Hospital, China Academy of Chinese Medical Sciences
Cooperation Center	Guangdong Province Hospital of Traditional Chinese Medicine
Center PI	Wenbin Fu
Review Method	Conference Review
Committee Members	Xing Zeng, Xiaohui Qiu, Shuchai Xu, Xusheng Liu, Lili Deng, Likai Li, Yong Li, Yijun Yu
Review Comments	According to 'Ethical Review Methods for Biomedical Study Involving Human Subjects' issued by the Ministry of Health, 'Management Specifications for Ethical Review of TCM Clinical Studies' issued by State Administration of Traditional Chinese Medicine, 'International Ethical Guidelines for Biomedical Research Involving Human Subjects' issued by Council for International Organizations of Medical Sciences, 'Declaration of Helsinki', the study protocol, informed consent, and recruitment documents of 'Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial' were approved by ethics committee of Guangdong Province Hospital of Traditional Chinese Medicine.
Statement of Ethics Committee	This approval will be duplicated in the ethics committee. Please feel free to contact the ethics committee if there is any query about the feasibility of the trial (the researcher's qualification or equipment). Researchers should notify the ethics committee if the trial is suspended, terminated, or completed. The ethics committee should be noticed if any severe adverse event occurs. An application for the re-review from ethics

	committee is need if the study protocol or informed consent is amended. Please notify the ethics committee if any protocol deviation occurs. Please do the continuing review according to the requested frequency stipulated by the ethics committee and submit the research progress report one month before the deadline.		
Validity Date	From May 09th, 2014 to May 09th, 2015	**Review Frequency**	Half a year Next review date: Nov 09, 2014
Contact	Juanjuan Gai, +86 020 81887233-30818		
Director Signature			
Institutional Ethics Committee of Guangdong Province Hospital of Traditional Chinese Medicine (Seal)			
May 09th, 2014			

武汉市第一医院
医学伦理委员会伦理审查批复件

武卫一院伦审【2014】3号

项目名称	电针和普芦卡必利治疗严重慢性便秘疗效比较——多中心随机对照试验		
申报单位	武汉市第一医院（武汉市中西医结合医院）针灸科		
项目负责人	张红星	伦理审批号	武卫一院伦审【2014】3号
审批伦理委员	武汉市第一医院医学伦理委员会		

伦理委员会收到以下相关文件：

（1）伦理审查申请、临床试验方案和临床研究可行性分析，技术的安全性、社会效益和经济效益分析

（2）知情同意书样本

（3）招募广告样本

（4）项目牵头单位中国中医科学院广安门医院伦理审查批件和实验药物的合格检验报告

（5）从事此项技术人员组成和履历

医学伦理委员会意见：

1、经本伦理委员会审查：同意我院针灸科参与中国中医科学院广安门医院牵头的电针和普芦卡必利治疗严重慢性便秘疗效比较——多中心随机对照试验

2、在项目开展过程中，应遵守国际《赫尔辛基宣言》及我国的伦理原则、道德标准及相关法律、法规、制度等。

3、每年向医学伦理委员会报告一次工作情况。如对病种、实施方案或知情同意书等进行任何修改，均应及时向医学伦理委员会书面报告，经同意后方可继续进行。

主 任 委 员：

批复日期：二〇一四年二月二十一日

武汉市第一医院 医学伦理委员会

声明：本委员会仅对备案的临床研究项目中涉及的伦理与道德问题负责

联系地址：武汉市中山大道215号，武汉市第一医院医学伦理委员会　邮编：430022
联系电话：027—85332012

Wuhan Hospital of Traditional Chinese and Western Medicine

Ethical Approval from the Ethics Committee

武卫一院伦审[2014] 3

Project Name	Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial		
Applicant	Wuhan Hospital of Traditional Chinese and Western Medicine		
Center PI	Hongxing Zhang	**Approval No.**	武卫一院伦审[2014] 3
Committee Members	Ethics Committee of Wuhan Hospital of Traditional Chinese and Western Medicine		

Approved Files:

(1) Ethical Review Application, Feasibility Analysis for the Study, Analysis for the Safety, Social Benefit and Economic Benefit of the Intervention;

(2) Informed Consent;

(3) Recruiting Advertisement;

(4) Ethical Approval for the Study of the Leading Center (Guang'anmen Hospital, China Academy of Chinese Medical Sciences);

(5) Personnel and the Resume of Researchers.

Review Comments:

1) The project of 'Electro-acupuncture versus prucalopride for severe chronic constipation: a multicenter, randomized, controlled trial' was approved to perform by ethics committee of Wuhan Hospital of Traditional Chinese and Western Medicine;
2) Please abide by the 'Declaration of Helsinki', and the ethical principle and related laws and regulations of China;
3) An application for the re-review from ethics committee is need if the study protocol or informed consent is amended. The researcher should do annual report for this project to ethic committee each year.

Director of the Ethics Committee:

Approval Date: Feb 21, 2014

Note: The ethics committee is only responsible for the ethical and moral issues of the documented clinical project.

Address: Ethics Committee of Wuhan Hospital of Traditional Chinese and Western Medicine, 215 Zhongshan Avenue, Wuhan, Hubei 430022
Contact Phone Number: +86 027 85332012