

Clinical Trial Registration Statement

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注册号: Registration number:	ChiCTR-IOR-14005744
最近更新日期: Date of Last Refreshed on:	2015-01-04
注册时间: Date of Registration:	2014-12-26
注册号状态:	预注册
Registration Status:	Prospective registration
注册题目:	腹部外科围手术期中西医结合快速康复技术的优化和推广应用研究
Public title:	Perioperative integrative medicine of fast track surgery and its application
注册题目简写:	
English Acronym:	
研究课题的正式科学名称:	中医药促进围手术期术后胃肠功能快速康复研究
Scientific title:	Research on Traditional Chinese Medicine for fast recovery of postoperative gastrointestinal function
研究课题代号(代码): Study subject ID:	
在二级注册机构或其它机构的注册号: The registration number of the Partner Registry or other register:	
申请注册联系人: 蒋志	研究负责人: 陈志强
Applicant: Jiang Zhi	Study leader: Chen Zhiqiang
申请注册联系人电话: Applicant telephone:	研究负责人电话: Study leader's telephone: +86 020-81887233
申请注册联系人传真: Applicant Fax:	研究负责人传真: Study leader's fax:
申请注册联系人电子邮件: Applicant E-mail:	研究负责人电子邮件: Study leader's E-mail: zhi57@163.com
申请单位网址(自愿提供): Applicant website(voluntary supply):	研究负责人网址(自愿提供): Study leader's website(voluntary supply):
申请注册联系人通讯地址: 广州市越秀区大德路111号	研究负责人通讯地址: 广州市越秀区大德路111号
Applicant address: No.111, Dade Road, Yuexiu District, Guangzhou, Guangdong, China	Study leader's address: No.111, Dade Road, Yuexiu District, Guangzhou, Guangdong, China
申请注册联系人邮政编码: Applicant postcode:	研究负责人邮政编码: Study leader's postcode:
申请人所在单位: 广东省中医院	
Applicant's institution: Guangdong Provincial Hospital of Traditional Chinese Medicine	
是否获伦理委员会批准: 是	
Approved by ethic committee: Yes	
伦理委员会批件文号: Approved No. of ethic committee:	伦理委员会批件附件: Approved file of Ethical Committee:
批准本研究的伦理委员会名称: 广东省中医院伦理委员会	
Name of the ethic committee: IRB of Guangdong Provincial Hospital of Traditional Chinese Medicine	
伦理委员会批准日期: Date of approved by ethic committee:	
伦理委员会联系人:	
Contact Name of the ethic committee:	
伦理委员会联系地址:	

伦理委员会联系人电话： Contact phone of the ethic committee:		伦理委员会联系人邮箱： Contact email of the ethic committee:			
研究实施负责（组长）单位：广东省中医院					
Primary sponsor:		Guangdong Provincial Hospital of Traditional Chinese Medicine			
研究实施负责（组长）单位地址：广州市越秀区大德路111号					
Primary sponsor's address:		No.111, Dade Road, Yuexiu District, Guangzhou, Guangdong, China			
试验主办单位(项目批准或申办者)： Secondary sponsor:	国家：	中国	省(直辖市)：	广东	市(区县)：
	Country:	China	Province:	Guangdong	City:
	单位(医院)：	广东省中医院	具体地址：	广州市越秀区大德路111号	
	Institution hospital:	Guangdong Provincial Hospital of Traditional Chinese Medicine	Address:	No.111, Dade Road, Yuexiu District, Guangzhou, Guangdong, China	
经费或物资来源：广州市科技计划项目					
Source(s) of funding:		Guangzhou science and technology plan project			
研究疾病：		腹腔镜结直肠癌术后			
Target disease:		laparoscopic surgery for colorectal cancer			
研究疾病代码：					
Target disease code:					
研究类型：		干预性研究			
Study type:		Interventional study			
研究所处阶段：		其它			
Study phase:		N/A			

研究目的：		观察围手术期中西医结合快速康复技术对腹腔镜结直肠癌术后患者快速康复的作用。	
Objectives of Study:		To observe the effectiveness of perioperative integrative medicine of fast track surgery on the recovery after laparoscopic surgery for colorectal cancer.	
药物成份或治疗方案详述：			
Description for medicine or protocol of treatment in detail:			
研究设计：		随机平行对照	
Study design:		Parallel	
纳入标准：		1) 腹腔镜结直肠癌术后患者。 2) 年龄：45-75岁之间。 3) 手术时间2-4小时者。 4) 麻醉时间2.5-4.5小时者。 5) 中医证型属于气滞气虚者。 6) 知情同意者。	
Inclusion criteria		1. Patients underwent laparoscopic surgery for colorectal cancer; 2. Aged from 45 to 75 years old; 3. The duration of operation is with 2 to 4 hours; 4. The anesthesia time is within 2.5 to 4.5 hours; 5. The TCM syndrome is identified as qi stagnation fu-organ stuff; 6. Willing to sign an informed consent document.	
排除标准：		1) 恶性肿瘤晚期出现恶液质、极度衰弱者。 2) 恶性肿瘤需扩大根治术者。 3) 有心血管、肝、肾、脑、肺等严重合并疾病者；高血压、糖尿病，药物控制效果不佳者。 4) 有精神疾病者。 5) 对治疗药物过敏者。 6) 孕妇或哺乳期者。 7) 重度营养不良患者，血清白蛋白<21g/L；前白蛋白< 0.10g/L。 8) 再次腹部手术并肠粘连严重者。 9) 术中出血量超过400毫升者，术中或术后需输血者。 10) 术后6小时内出现严重并发症者，或术后转ICU者，如多脏器功能不全。 11) 术后需行腹腔热灌注者。 12) 急诊手术者。 13) 术后必须使用对胃肠功能有明显影响的药物或治疗者。	

	14) 目前正在参加或在本研究前1个月内参加过其它临床试验的患者。 15) 研究者认为不宜进行此项临床研究。				
Exclusion criteria:	1. Advanced malignant tumor cachexia, extremely weak; 2. Patients of malignant tumor who needs extended radical operation; 3. patients combined with cardiovascular, liver, kidney, brain, lung and other serious diseases, Bad drug control of Hypertension, diabetes; 4. Patients with mental disease; 5. Patients with allergies to the intervention; 6. Pregnant or breast-feeding women; 7. Severe malnutrition, serum albumin less than 21g/L, prealbumin less than 0.1g/L; 8. Re-abdominal surgery and severe intestinal adhesion; 9. Blood loss more than 400 milliliters during the surgery; 10. Occuring serious complications within 6 hours after the surgery, e.g. multiple organ dysfunction; 11. Postoperative intraperitoneal hyperthermic perfusion; 12. Emergency surgery; 13. Prokinetic drugs must be taken after operation; 14. Patient participating other clinical study or having participated other clinical study in the last one month; 15. Patient considered inappropriate to participate the study by clinical investigators.				
研究实施时间: Study execute time:	从From2014-06-01至To 2017-06-30				
干预措施: Interventions:	组别:	干预组	样本量:		
	Group:	Intervental Group	Sample size:		
	干预措施:	中西医结合干预措施	干预措施代码:		
	Intervention:	integrative medicine intervention	Intervention code:		
	组别:	对照组	样本量:		
	Group:	Control Group	Sample size:		
	干预措施:	基础治疗	干预措施代码:		
	Intervention:	Basic intervention	Intervention code:		
研究实施地点: Countries of recruitment and research settings:	国家:	中国	省(直辖市):	广东	市(区县):
	Country:	China	Province:	Guangdong	City:
	单位(医院):	广州中医药大学第一附属医院	单位级别:	三级甲等	
	Institution hospital:	The first affiliated hospital of Guangzhou University of Traditional Chinese Medicine	Level of the institution:	Tertiary A hospital	
	国家:	中国	省(直辖市):	广东	市(区县):
	Country:	China	Province:	Guangdong	City:
	单位(医院):	广东省中山市中医院	单位级别:	三级甲等	
	Institution hospital:	Hospital of Traditional Chinese Medicine of Zhongshan	Level of the institution:	Tertiary A hospital	
	国家:	中国	省(直辖市):	广东	市(区县):
	Country:	China	Province:	Guangdong	City:
	单位(医院):	广东省中西医结合医院	单位级别:	三级甲等	
	Institution hospital:	Integrative hospital of Guangdong province	Level of the institution:	Tertiary A hospital	
	国家:	中国	省(直辖市):	广东	市(区县):
	Country:	China	Province:	Guangdong	City:
	单位(医院):	广东省中医院	单位级别:	三级甲等	
	Institution hospital:	Guangdong Provincial Hospital of Traditional Chinese Medicine	Level of the institution:	Tertiary A hospital	
指标中文名:	术后首次肠鸣音恢复时间		指标类型:	主要指标	

测量指标: Outcomes:	指标中文名:	术后首次肠鸣音恢复时间	指标类型:	主要指标
	Outcome:	time to first bowel sounds	Type:	Primary indicator
	测量时间点:		测量方法:	
	Measure time point of outcome:		Measure method:	
	指标中文名:	术后首次排气恢复正常时间	指标类型:	主要指标
	Outcome:	time to first flatus	Type:	Primary indicator
	测量时间点:		测量方法:	
	Measure time point of outcome:		Measure method:	
	指标中文名:	术后首次排便时间	指标类型:	主要指标
	Outcome:	time to first defecation	Type:	Primary indicator
	测量时间点:		测量方法:	
	Measure time point of outcome:		Measure method:	
	指标中文名:	胃肠激素	指标类型:	主要指标
	Outcome:	Gastrointestinal hormones	Type:	Primary indicator
	测量时间点:		测量方法:	
	Measure time point of outcome:		Measure method:	
	指标中文名:	疲劳评分	指标类型:	主要指标
	Outcome:	fatigue evaluation	Type:	Primary indicator
	测量时间点:		测量方法:	
	Measure time point of outcome:		Measure method:	
	指标中文名:	康复量表	指标类型:	主要指标
	Outcome:	recovery scale	Type:	Primary indicator
	测量时间点:		测量方法:	
	Measure time point of outcome:		Measure method:	
	指标中文名:	胃肠动力恢复评价	指标类型:	附加指标
	Outcome:	Gastrointestinal motility scale	Type:	Additional indicator
	测量时间点:		测量方法:	
	Measure time point of outcome:		Measure method:	
采集人体标本: Collecting sample(s) from participants:	标本中文名:	血液	组织:	
	Sample Name:	Blood	Tissue:	
	人体标本去向	使用后销毁	说明	
	Fate of sample:	Destruction after use	Note:	
招募研究对象情况: Recruiting status:		正在进行 Recruiting	年龄范围: Participant age:	最小 Min age 45 岁 years 最大 Max age 75 岁 years
性别:		男女均可	Gender:	Both
随机方法 (请说明由何人用什么方法产生随机序列): 本研究按照分层随机方法, 通过网络系统实现。				

随机方法（请说明由何人用什么方法产生随机序列）：	本研究按照分层随机方法，通过网络系统实现。
Randomization Procedure (please state who generates the random number sequence and by what method):	stratified random according to internet system
盲法:	
Blinding:	
试验完成后的统计结果（上传文件）：	点击下载
Calculated Results after the Study Completed(upload download file):	
原始数据公开时间: The time of sharing IPD:	即时公开/Real time access
共享原始数据的方式（说明：请填入公开原始数据日期和方式，如采用网络平台，需填该网络平台名称和网址）：	
The way of sharing IPD"(include metadata and protocol, If use web-based public database, please provide the url):	
数据采集和管理（说明：数据采集和管理由两部分组成，一为病例记录表(Case Record Form, CRF)，二为电子采集和管理系统(Electronic Data Capture, EDC)，如ResMan即为一种基于互联网的EDC:	
Data collection and Management (A standard data collection and management system include a CRF and an electronic data capture:	
数据管理委员会: Data Managemen Committee:	暂未确定/Not yet