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检索试验

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按征募研究对象情况统计

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质子泵抑制剂联合微生态制剂治疗反流性食管炎对肠道菌群影响的临床研究

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注册号: Registration number:	ChiCTR1800018218		
最近更新日期: Date of Last Refreshed on:	2018-09-05		
注册时间: Date of Registration:	2018-09-05		
注册号状态:	补注册		
Registration Status:	Retrospective registration		
注册题目:	质子泵抑制剂联合微生态制剂治疗反流性食管炎对肠道菌群影响的临床研究		
Public title:	A Clinical Study for Effects on the Intestinal Microbiota of Proton Pump Inhibitor and Probiotics in the treatment of Reflux Esophagitis		
注册题目简写:			
English Acronym:			
研究课题的正式科学名称:	质子泵抑制剂联合微生态制剂治疗反流性食管炎对肠道菌群影响的临床研究		
Scientific title:	A Clinical Study: Reflux Esophagitis Treated with Proton Pump Inhibitor and Probiotics has Effects on the Intestinal Microbiota		
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: 孙清华	研究负责人: 孙士东		
Applicant: Sun Qinghua	Study leader: Sun Shidong		
申请注册联系人电话: Applicant telephone:	研究负责人电话: Study leader's telephone:		+86 18553376767
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:		13964326567@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: 山东省淄博市临淄区太公路65号	研究负责人通讯地址: 山东省淄博市临淄区太公路65号		
Applicant address: 65 Taigong Road, Linzi District, Zibo, Shandong, China	Study leader's address: 65 Taigong Road, Linzi District, Zibo, Shandong, 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: 北京大学			
Applicant's institution: Peking University			
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: 2015-KY-003	伦理委员会批件附件: Approved file of Ethical Committee: 查看附件View		
批准本研究的伦理委员会名称: 齐鲁石化医院集团中心医院医学伦理委员会			
Name of the ethic committee: Medical Ethics Committee of Central Hospital of Qilu Petrochemical Group			
伦理委员会批准日期: Date of approved by ethic committee: 2013-08-26			
伦理委员会联系人: 徐飞			
Contact Name of the ethic committee: Xu Fei			
伦理委员会联系地址: 山东省淄博市临淄区太公路65号			
Contact Address of the ethic committee: 65 Taigong Road, Linzi District, Zibo, Shandong, China			
伦理委员会联系人电话: Contact phone of the ethic committee: +86 18553377189	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: 北大医疗鲁中医院			
Primary sponsor: PKU Care Luzhong Hospital			
研究实施负责 (组长) 单位地址: 山东省淄博市临淄区太公路65号			
Primary sponsor's address: 65 Taigong Road, Linzi District, Zibo, Shandong, 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): 山东省	市(区县): 淄博市
	Country: China	Province: Shangdong	City: Zibo
	单位(医院): 北大医疗鲁中医院	具体地址: 山东省淄博市临淄区太公路65号	
	Institution hospital: PKUCare Luzhong Hospital	Address: 65 Taigong Road, Linzi District, Zibo, Shandong, China	
经费或物资来源: 山东省医药卫生科技发展计划项目			
Source(s) of funding: Shandong medical science and technology development project			
研究疾病: 反流性食管炎			
Target disease: reflux esophagitis			
研究疾病代码: K21.0			
Target disease code: K21.0			
研究类型: 干预性研究			
Study type: Interventional study			
研究所处阶段: 上市后药物			
Study phase: Post-market			
研究目的:		观察质子泵抑制剂治疗反流性食管炎对肠道菌群影响、联用微生态制剂治疗后对肠道菌群的影响, 及反流性食管炎的发生与小肠细菌过增长有无相关性; 希望通过该项研究, 为胃食管反流病患者提供更加行之有效的治疗方案, 既能达到更佳的治疗效果减少复发, 又能减少长期服用药物带来不良反应, 为胃食管反流病患者带来福音。	
Objectives of Study:		To observe the effect of proton pump inhibitors on the intestinal flora ,and the effect on the intestinal flora after the combination of probiotics, and the correlation between the occurrence of reflux esophagitis and the growth of intestinal bacteria. It is hoped that through this research, patients with gastroesophageal reflux disease will be provided with more effective treatments, which can achieve better therapeutic effects, reduce recurrence, and reduce adverse reactions caused by long-term use of drugs.	
药物成份或治疗方案详述:			
Description for medicine or protocol of treatment in detail:			
研究设计: 随机平行对照试验			
Study design: Randomized parallel controlled trial			
纳入标准: 1.同意应用艾司奥美拉唑治疗, 且未曾服用PPI或者停用PPI治疗至少6个月以上的RE患者。年龄20~ 65岁。RE诊断依据: 2015 ASGE指南内镜在GERD管理中的作用及洛杉矶分型标准A-D级。2.近4周内未使用抗生素、益生菌、乳果糖、其他制酸药或促进胃肠动力药物, 未行过各种灌肠术。3.肝功及肾功正常。4.LHBT检查SIBO阴性。			

Inclusion criteria	1. Patients who have been treated with Esomeprazole and have not taken PPI or discontinued PPI for at least 6 months. Aged 20 to 65 years old. RE diagnosis based on: 2015 ASGE guidelines for endoscopy in GERD management and the Los Angeles classification criteria A-D; 2. No antibiotics, probiotics, lactulose, other antacids or gastrointestinal motility drugs have been used in the past 4 weeks. Various enema procedures have not been performed; 3. Liver function and kidney function are normal; 4. LHBT check for SIBO is negative.		
排除标准:	既往有肝硬化、肾功能不全、肿瘤、甲状腺疾病、糖尿病、克罗恩病、溃疡性结肠炎等病史；合并肝、胆、胰腺疾病所致的腹泻、吸收不良及便秘等；既往胃肠道或腹部外科手术史；按照罗马III标准，符合肠易激综合征诊断者；未达到诊断标准，但有腹胀、腹泻或者便秘症状持续3月以上者。		
Exclusion criteria:	Medical history includes: cirrhosis, renal insufficiency, tumor, thyroid disease, diabetes, Crohn's disease, ulcerative colitis, etc.; combined with diarrhea, malabsorption and constipation caused by liver, gallbladder, pancreatic disease ; previous operation history of gastrointestinal tract and/or abdominal surgery; according to the Rome III criteria, diagnoses of irritable bowel syndrome; did not meet the Rome III diagnostic criteria, but have abdominal distension, diarrhea or constipation symptoms lasting more than 3 months.		
研究实施时间: Study execute time:	从From 2014-01-01 至To 2015-12-31		
干预措施: Interventions:	组别:	试验组	样本量:
	Group:	Group 1	Sample size:
	干预措施:	艾司奥美拉唑+枯草杆菌二联活菌肠溶胶囊	干预措施代码:
	Intervention:	esomeprazole+Medilac-S	Intervention code:
	组别:	安慰剂组	样本量:
	Group:	Group 2	Sample size:
	干预措施:	艾司奥美拉唑+安慰剂	干预措施代码:
	Intervention:	esomeprazole+placebo	Intervention code:
研究实施地点: Countries of recruitment and research settings:	国家:	中国	省(直辖市): 山东
	Country:	China	Province: Shandong
	单位(医院):	北大医疗鲁中医院	单位级别: 三级甲等
	Institution hospital:	PKUCare Luzhong Hospital	Level of the institution: Tertiary A Hospital
测量指标: Outcomes:	指标中文名:	乳果糖氢呼气试验	指标类型: 主要指标
	Outcome:	lactulose hydrogen breath test	Type: Primary indicator
	测量时间点:		测量方法:
	Measure time point of outcome:		Measure method:
	指标中文名:	反流性疾病问卷	指标类型: 主要指标
	Outcome:	reflux diagnostic questionnaire	Type: Primary indicator
	测量时间点:		测量方法:
	Measure time point of outcome:		Measure method:
	指标中文名:	胃镜检查	指标类型: 主要指标
	Outcome:	gastroscope	Type: Primary 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)	标本中文名:	血液	组织: 静脉血
	Sample Name:	Blood	Tissue: venous blood
	人体标本去向	使用后保存	说明: 液氮保存
	Fate of sample:	Preservation after use	Note:

from participants:	标本中文名:	食管食管胃连接处粘膜	组织:	食管食管胃连接处
	Sample Name:	mucosa of esophagus-gastric junction	Tissue:	esophagus-gastric junction
	人体标本去向	使用后保存	说明	液氮保存 及 石蜡切片
	Fate of sample:	Preservation after use	Note:	

招募研究对象情况:	正在进行	年龄范围:	最小 Min age	20 岁 years
Recruiting status:	Recruiting	Participant age:	最大 Max age	65 岁 years

性别:	男女均可	Gender:	Both
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随机方法 (请说明由何人用什么方法产生随机序列):

与招募工作无关的工作人员采用随机数表法产生随机序列。

Randomization Procedure (please state who generates the random number sequence and by what method):

The random sequence was generated from the random number table by staff who are not related to recruitment.

盲法:	随机, 单盲。
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Blinding:	Random, single-blind trial.
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原始数据公开时间:

The time of sharing IPD:

试验完成后6个月内公开/Within six months after the trial complete

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):

通过ResMan共享数据

The way of sharing IPD”(include metadata and protocol, If use web-based public database, please provide the url):

IPD will be accessible via ResMan

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:

Excel

Data collection and Management (A standard data collection and management system include a CRF and an electronic data capture:

Excel

数据管理委员会:	暂未确定/Not yet
Data Managemen Committee:	

返回列表



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中国临床试验注册中心 - 世界卫生组织国际临床试验注册平台一级注册机构

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深圳市润科电子商务有限公司

粤ICP备13012814号-2

提示: 推荐使用IE8.0以上版本 宽屏显示分辨率下使用系统。