评价中药从脾论治治疗痞满（功能性消化不良)多中心、随机、双盲、安慰剂对照临床研究

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注册号： Registration number：	ChiCTR-TRC-13003200
最近更新日期： Date of Last Refreshed on：	2016-02-01
注册时间： Date of Registration：	2013-04-19
注册号状态：	预注册
Registration Status：	Prospective registration
注册题目：	评价中药从脾论治治疗痞满（功能性消化不良)多中心、随机、双盲、安慰剂对照临床研究
Public title：	A Multicenter, Randomized, Double-blind, Placebo-controlled, Clinical study to evaluate the efficacy of Chinese medicine on patients with functional dyspepsia by differential treatment of spleen
研究课题的正式科学名称：	脾失健运所致功能性胃肠疾病从脾论治疗效机制及规律研究
Scientific title：	The Study on Mechanism, Diagnosis andTreatment Regularity of differential treatment of spleen for functional gastrointestinal diseases caused by dysfunction of the spleen
研究课题代号(代码)： Study subject ID：	2013CB531703
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：	康楠	研究负责人：	唐旭东
Applicant：	Kangnan	Study leader：	Xudong Tang
申请注册联系人电话： Applicant telephone：	+86 18811505325	研究负责人电话： Study leader's telephone：	+86 13901137632
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：	kangnan.1988@163.com	研究负责人电子邮件： Study leader's E-mail：	kangnan.1988@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：	北京市海淀区西苑操场1号，中国中医科学院西苑医院 消化科	研究负责人通讯地址：	北京市海淀区西苑操场1号，中国中医科学院西苑医院 消化科
Applicant address：	1 Xiyuan Caochang, Haidian District, Beijing, China	Study leader's address：	1 Xiyuan Caochang, Haidian District, Beijing, China
申请注册联系人邮政编码： Applicant postcode：	100091	研究负责人邮政编码： Study leader's postcode：	100091
申请人所在单位：	中国中医科学院西苑医院		
Applicant's institution：	Xiyuan Hospital Affiliated to China Academy of Chinese Medical Sciences		
是否获伦理委员会批准：	是		

Traditional Chinese Medicine Xiang-sha-liu-jun Granules in Patients With Postprandial Distress Syndrome(PDS)

This study is currently recruiting participants. (see Contacts and Locations)

Verified April 2016 by Xiyuan Hospital of China Academy of Chinese Medical Sciences

Sponsor:
Xiyuan Hospital of China Academy of Chinese Medical Sciences

Collaborators:
The First Affiliated Hospital, Guangzhou University of Traditional Chinese Medicine
Wuhan Integrated TCM and Western Medicine Hospita

Information provided by (Responsible Party):
Xiyuan Hospital of China Academy of Chinese Medical Sciences

ClinicalTrials.gov Identifier:
NCT02762136

First received: April 27, 2016
Last updated: May 4, 2016
Last verified: April 2016
History of Changes

Purpose

Functional dyspepsia (FD), which is one of the most common gastrointestinal disorders with high disease burden. Postprandial distress syndrome (PDS) is a common subtype of FD. Although the effectiveness of Chinese herbal formula of Xiang-sha-liu-jun granule (XSLJG) for alleviating PDS symptoms has been assessed in previous studies, more convinced evidence of randomized placebo-controlled study is needed.

Condition	Intervention	Phase
Postprandial Distress Syndrome	Drug: placebo Drug: Xiang-sha-liu-jun granules	Phase 1 Phase 2

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: Xiang-sha-liu-jun Granules as an Herbal Formula for the Treatment of Postprandial Distress Syndrome(PDS): a Prospective, Double-blinded, Randomized and Placebo-controlled,Three-center Trial

Further study details as provided by Xiyuan Hospital of China Academy of Chinese Medical Sciences:

Primary Outcome Measures:

- change of postprandial discomfort severity Scale [Time Frame: Postprandial Discomfort Severity Scale at baseline, 2 weeks, and 4 weeks during oral administration of medicine] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- global impression scale [Time Frame: global impression scale at baseline, 2 weeks, and 4 weeks during oral administration of medicine] [Designated as safety issue: Yes]
- SF-36 questionnaire [Time Frame: SF-36 questionnaire at baseline, 2 weeks, and 4 weeks during oral administration of medicine] [Designated as safety issue: Yes]
- gastric emptying [Time Frame: gastric emptying will be assessed at baseline and 4 weeks during oral administration of medicine] [Designated as safety issue: Yes]

  Gastric emptying is related with several hormones such as CCK and ghrelin.

Estimated Enrollment: 216
Study Start Date: August 2015
Estimated Study Completion Date: April 2018
Estimated Primary Completion Date: December 2017 (Final data collection date for primary outcome measure)