



系统首页Index 新注册项目New Project 项目中心project 公司用户companys 个人资料personal 密码修改password 意见反馈feedback

当前位置position: 首页index > 修改项目信息edit project

修改项目信息edit project

审核状态: Project audit state:	该项目已经通过审核, 不能再修改项目信息。 This trial has been verified, you can't edit it any more. 返回Back		
注册号: Registration number:	ChiCTR1900028529		
最近更新日期: Date of Last Refreshed on:	2019/12/27 8:55:59		
注册号状态:	预注册		
Registration Status:	1008001 Prospective registration		
注册题目:	超声评估糖尿病患者术前饮用不同剂量碳水化合物胃容量		
Public title:	Ultrasound assessment of gastric volume in diabetic patients who drink different doses of carbohydrates on preoperative		
研究课题的正式科学名称:	超声评估糖尿病患者术前饮用不同剂量碳水化合物胃容量		
Scientific title:	Ultrasound assessment of gastric volume in diabetic patients who drink different doses of carbohydrates on preoperative		
研究课题代号(代码): Study subject ID:			
在其它机构的注册号: Secondary ID:			
申请注册联系人:	林新强	研究负责人:	林新强
Applicant:	Xinqiang Lin	Study leader:	Xinqiang Lin
申请注册联系人电话: Applicant telephone:	+86 13646983330	研究负责人电话: Study leader's telephone:	+86 13646983330
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:	894651884@qq.com	研究负责人电子邮件: Study leader's E-mail:	894651884@qq.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):	
申请注册单位通讯地址: Applicant address:	福建省莆田市荔城区东圳东路999号	研究负责人通讯地址: Study leader's address:	福建省莆田市荔城区东圳东路999号
Applicant address:	999 East Dongzhen Road, Putian, Fujian, China	Study leader's address:	999 East Dongzhen Road, Putian, Fujian, China
申请注册单位邮政编码: Applicant postcode:	351100	研究负责人邮政编码: Study leader's postcode:	
申请人所在单位:	莆田学院附属医院		
Applicant's institution:	Department of Anesthesiology, Affiliated Hospital of Putian 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:	南医附伦201936	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: Name of the ethic committee:	莆田学院附属医院伦理委员会		
Ethic Committee of Affiliated Hospital of Putian University			
伦理委员会批准日期: Date of approved by ethic committee:	2018/11/20		
伦理委员会联系人: Contact Name of the ethic committee:	刘丽雪		
Lixue Liu			
伦理委员会联系地址: Contact Address of the ethic committee:	福建省莆田市荔城区东圳东路999号		
999 East Dongzhen Road, Putian, Fujian, China			
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: Primary sponsor:	莆田学院附属医院		
Affiliated Hospital of Putian University			
研究实施负责(组长)单位地址: Primary sponsor's address:	福建省莆田市荔城区东圳东路999号		
999 East Dongzhen Road, Putian, Fujian, China			
国家:	中国	省(直辖市):	福建
City:	China	Province:	Fujian
市(区县):	莆田	City:	PuTian
试验主办单位(项目批准或申办者): Secondary sponsor:	莆田学院附属医院		
单位(医院):	莆田学院附属医院	具体地址:	福建省莆田市荔城区东圳东路999号
Institution hospital:	Affiliated Hospital of Putian University	Address:	999 East Dongzhen Road

经费或物资来源:	莆田学院附属医院科研基金		
Source(s) of funding:	Research fundings of Affiliated Hospital of Putian University		
研究疾病:	糖尿病		
Target disease:	Diabetes		
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:	探索性研究/预试验		
Study phase:	0		
研究目的:	围术期应用超声评估胃容量已成为研究的热点。通过对行择期手术糖尿病患者术前2小时饮用不同剂量的碳水化合物胃容量超声评估的研究, 设计随机对照试验, 测量评估, 计算胃窦部横截面积和胃容量, 每公斤体重胃容量及监测毛细血管血糖变化。评估围术期糖尿病患者术前2小时饮用碳水化合物合剂剂量。		
Objectives of Study:	The application of ultrasound to evaluate gastric volume in perioperative period has become a focus of research. Objective to study the ultrasound assessment of in those who underwent elective surgery in diabetic patients drink different doses of carbohydrate 2 hours before surgery. randomized controlled trials were design semi-quantitative rating was conducted, calculate the gastric antrum cross-sectional area, gastric volume, and gastric volume per kilogram of body weight, monitor capillary blood glucose. To assess the appropriate dose of carbohydrate for patients with perioperative diabetes 2 hours before surgery.		
研究设计:	随机平行对照		
Study design:	Parallel		
纳入标准:	1. 年龄40-80岁 2. ASA I-III级 3. 确诊糖尿病 4. 全身麻醉行择期手术患者 5. 自愿并签署知情同意书。		
Inclusion criteria:	1. Patients aged from 40 to 80 years old; 2. ASA grades 1-3; 3. diagnosis of diabetes; 4. Patients undergoing elective surgery under general anesthesia; 5. Written consent was obtained from all participants.		
排除标准:	妊娠、心肾功能不全、甲状腺功能减低、肥胖患者 (BMI>35kg/m ²)、器质性消化系统疾病,如:胃食管反流、消化道溃疡或肿瘤、胆石症、上消化道手术史,术前接受动力药物治疗及术前进行胃肠减压或胃空肠营养者,拒绝或无法配合本研究。		
Exclusion criteria:	Pregnancy, Those who had any Cardiac and renal insufficiency, Those who had hypothyroidism Obesity (BMI > 35 kg/m ²), Those who had organic digestive system diseases such as gastroesophageal reflux, gastrointestinal ulcers or tumors, cholelithiasis, history of upper gastrointestinal surgery, preoperative anti-nausea drugs affect drug therapy and on preoperative gastrointestinal decompression or stomach jejunum nutrition, Those who rejected or unable to cooperate with the study.		
研究实施时间:	从2019/12/01至2020/12/01		
Study execute time:			
干预措施: Interventions:	组别:	A组	样本量:
	Group:	Group A	Sample size: 15
	干预措施:	术前2小时未饮用碳水化合物	干预措施代码:
	Intervention:	A组	Intervention code:
	组别:	B组	样本量:
	Group:	Group B	Sample size: 15
	干预措施:	术前2小时饮用100毫升碳水化合物	干预措施代码:
	Intervention:	B组	Intervention code:
	组别:	C组	样本量:
	Group:	Group C	Sample size: 15
	干预措施:	术前2小时饮用200毫升碳水化合物	干预措施代码:
	Intervention:	C组	Intervention code:
干预措施: Interventions:	组别:	D组	样本量:
	Group:	Group D	Sample size: 15
	干预措施:	术前2小时饮用300毫升碳水化合物	干预措施代码:
	Intervention:	D组	Intervention code:
研究实施地点: Countries of recruitment and research settings:	国家:	中国	省(直辖市): 福建
	Country:	China	Province: Fujian
	市(区县):	莆田	City: PuTian
	单位(医院):	莆田学院附属医院	单位级别: 三级甲等
研究实施地点: Countries of recruitment and research settings:	Institution:	Affiliated Hospital of Putian University	Level of the institution: Tertiary A hospital
测量指标: Outcomes:	指标中文名:	胃窦部横截面积	
	Outcome:	antral cross-sectional area	
	测量时间点:	测量方法:	
	Measure time point of outcome:	Measure method:	
测量指标: Outcomes:	指标中文名:	胃容量	
	Outcome:	gastric volume	
	测量时间点:	测量方法:	
	Measure time point of outcome:	Measure method:	
测量指标: Outcomes:	指标中文名:	每公斤体重胃容量	
	Outcome:	gastric volume per kilogram of body weight	
	测量时间点:	测量方法:	
	Measure time point of outcome:	Measure method:	
测量指标: Outcomes:	指标中文名:	Perlas A量表半定量分级评估	
	Outcome:	Perlas A scale semi-quantitative grading assessment	
	测量时间点:	测量方法:	
	Measure time point of outcome:	Measure method:	

Measure time point of outcome:	Measure method:
指标中文名: 低血糖和胃容量误吸发生率	
Outcome: Incidence of hypoglycemia and gastric volume aspiration	
测量时间点:	测量方法:
Measure time point of outcome:	Measure method:
指标中文名: 末梢毛细血管血糖	
Outcome: Peripheral blood glucose	
测量时间点:	测量方法:
Measure time point of outcome:	Measure method:
指标中文名: 胃容量>1.5ml/kg 发生率	
Outcome: Probability of gastric volume > 1.5ml/kg	
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:

征募研究对象情况: Recruiting status:	尚未开始 Not yet recruiting	年龄范围: Participant age:	最小 Min age: 40 岁 years 最大 Max age: 80 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): 计算机产生随机数字序列表

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

盲法: 未说明

Blinding: Not stated

是否公开试验完成后的统计结果:
Calculated Results after the Study Completed public access: ☒ 公开Public ☐ 变更change

上传的试验完成后的统计结果:
Statistical results after completion of the test file upload: 浏览 *

UTN(全球唯一识别码):

是否共享原始数据:
IPD sharing: 否No

共享原始数据的方式 (说明: 请填写公开原始数据日期和方式, 如采用网络平台, 请填写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): Affiliated Hospital of Putian University

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即作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): Affiliated Hospital of Putian University

数据与安全监察委员会:
Data and Safety Monitoring Committee: 有/Yes暂未确定/Not yet

研究计划书或研究报告发表信息 (杂志名称、期、卷、页、时间; 或网址):

Publication information of the protocol/research results report (name of the journal, volume, issue, pages, time, or website):

注册人:
Name of Registration: 2019/12/26

项目来源:
Project Origin: 本站

返回Back

提示: 推荐使用IE8.0以上版本 宽屏显示分辨率下使用系统。

Copyright(c) (2005 - 2015) ChiCTR.org All rights reserved. 中国临床试验注册中心 版权所有
深圳启奥华科技有限公司