

我建立的项目The project created by myself

项目筛选条件 Search Options			
注册题目 Public title	<input type="text"/>	正式科学名称 Scientific title	<input type="text"/>
审核状态 Verify status	<div>不限/All</div>	注册号 Registration number	<input type="text"/>
		研究课题代号(代码) Subject ID	<input type="text"/>
		在其它机构的注册号 Secondary number	<input type="text"/>
<div>筛选 Search</div> 展开更多筛选条件More			

注册号 Registration number	注册题目 Public title	审核状态 State	注册时间 Reg Date	操作 Operate
ChiCTR-OOC-17010617	炎症性肠病患者TPMT和NUDT15基因多态性与硫唑嘌呤所致不良反应关系的研究 Study on the relationship between TPMT and NUDT15 gene polymorphism and azathioprine-induced adverse reactions in patients with inflammatory bowel disease	通过审核 Successful	2017/2/12 0:00:00	<div>编辑Edit</div>

注：项目一旦通过审核，项目注册信息将不能进行修改，如需更正，请联系管理人员。

审核状态： 该项目已通过审核，不能再修改项目信息。
Project audit state:

返回Back

注册号: Registration number:	ChiCTR-OOC-17010617
最近更新日期: Date of Last Refreshed on:	2017/2/12 20:30:05
注册号状态: Registration Status:	预注册 1008001 Prospective registration
注册题目: Public title:	炎症性肠病患者TPMT和NUDT15基因多态性与硫唑嘌呤所致不良反应关系的研究 Study on the relationship between TPMT and NUDT15 gene polymorphism and azathioprine-induced adverse reactions in patients with inflammatory bowel disease
研究课题的正式科学名称: Scientific title:	炎症性肠病患者TPMT和NUDT15基因多态性与硫唑嘌呤所致不良反应关系的研究 Study on the relationship between TPMT and NUDT15 gene polymorphism and azathioprine-induced adverse reactions in patients with inflammatory bowel disease
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: Applicant:	王红慧 Wang Honghui
研究负责人: Study leader:	王红慧 Wang Honghui
申请注册联系人电话: Applicant telephone:	+86 15111286874
研究负责人电话: Study leader's telephone:	+86 15111286874
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:	whh_xy@126.com
研究负责人电子邮件: Study leader's E-mail:	whh_xy@126.com
申请注册联系人电子邮件: Applicant E-mail:	whh_xy@126.com
研究负责人电子邮件: Study leader's E-mail:	whh_xy@126.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: Applicant address:	湖南省长沙市开福区湘雅路87号 87 Xiangya Road, Kaifu district, Changsha, Hunan, China
研究负责人通讯地址: Study leader's address:	湖南省长沙市开福区湘雅路87号 87 Xiangya Road, Changsha, Hunan, 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: Applicant's institution:	中南大学湘雅医院 Xiangya Hospital, Central South University
是否获伦理委员会批准: Approved by ethic committee:	是 Yes
伦理委员会批准文号: Approved No. of ethic committee:	201702016
伦理委员会批准附件: Approved file of Ethical Committee:	
批准本研究的伦理委员会名称: Name of the ethic committee:	中南大学湘雅医院医学伦理委员会 Xiangya Hospital Central South University Medical Ethics Committee
伦理委员会批准日期: Date of approved by ethic committee:	1990/01/01
伦理委员会联系人: Contact Name of the ethic committee:	
伦理委员会联系地址: Contact Address of the ethic committee:	
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：中南大学湘雅医院	
Primary sponsor: Xiangya Hospital, Central South University	
研究实施负责（组长）单位地址：湖南省长沙市开福区湘雅医院	
Primary sponsor's address: 87 Xiangya Road, Kaifu district, Changsha, Hunan, China	
<div>国家：中国省(直辖市)：湖南省市(区县)：</div> <div>Country: ChinaProvince: HunanCity:</div>	
试验主办单位(项目批准或申办者)：Secondary sponsor:	单位(医院)：中南大学湘雅医院
	具体地址：湖南省长沙市开福区87
<div>Institution hospital: Xiangya Hospital, Central South UniversityAddress: 87 Xiangya Road, Kaifu district, Changsha, Hunan, China</div>	
经费或物资来源：医院科研经费	
Source(s) of funding: Hospital Research Funds	
研究疾病：炎症性肠病	
Target disease: Inflammatory Bowel Disease	
研究疾病代码：	
Target disease code:	
研究类型：观察性研究	
Study type: Observational study	
研究所处阶段：其它	
Study phase: Other	
研究目的：研究TPMT以及NUDT15基因多态性是否与炎症性肠病患者使用硫唑嘌呤治疗出现的不良反应相关，指导炎症性肠病的个体化治疗。	
Objectives of Study: Study on the relationship between TPMT and NUDT15 gene polymorphism and azathioprine-induced adverse reactions in patients with inflammatory bowel disease. And provide a guidance of individual medical therapy to inflammatory bowel disease.	
研究设计：队列研究	
Study design: Cohort study	

纳入标准：1.确诊炎症性肠病患者（临床诊断和或病理诊断）；2.年龄16-70岁，男女不限；3.签署知情同意书。

Inclusion criteria1. Diagnosis of inflammatory bowel disease (clinical diagnosis and / or pathological diagnosis); 2. Aged from 16 to 70 years old, male or female; 3. Sign the informed consent form.

排除标准：1.严重心脏和（或）肝肾功能不全；2.粘膜活检为癌或淋巴瘤；3.活动性结核病；4.活动性病毒性肝炎；存在明显的转氨酶升高（大于正常值上限2倍），和或乙肝大三阳且病毒复制DNA>10^5copies/ml或小二阳病毒复制大于10^4copies/ml；5.合并细菌或病毒感染未得到有效控制；6.急腹症，或有其他手术适应症（会合并重复瘘、纤维性狭窄致肠梗阻等）。

Exclusion criteria1. Severe heart and (or) liver and kidney dysfunction; 2. Mucosal biopsy implied cancer or lymphoma; 3. Active tuberculosis; 4. Active viral hepatitis: significant elevated transaminase (greater than 2 times the upper limit of normal), and / or hepatitis B HBeAg and viral replication DNA> 10^5copies / ml or small positive virus replication greater than 10^4copies / ml; 5.Complication with bacterial or viral infection has not been effectively controlled; 6. Acute abdomen, or other indications for surgery (complicated with fistula, fibrous stenosis caused by intestinal obstruction, etc.).

研究实施时间：从2017/02/13至2018/03/30

Study execute time: From2017/02/13To 2018/03/30

干预措施：Interventions:	组别：2	样本量：150
	Group: Two cohorts	Sample size:
	干预措施：硫唑嘌呤治疗	干预措施代码：
	Intervention: 2	Intervention code:

研究实施地点：Countries of recruitment and research settings:

国家：中国省(直辖市)：湖南省市(区县)：

Country: ChinaProvince: HunanCity:

单位(医院)：中南大学湘雅医院单位级别：三级甲等

Institution hospital: Xiangya Hospital Central South UniversityLevel of the institution: Tertiary A hospital

测量指标：Outcomes:

指标中文名：NUDT15基因多态性

Outcome: NUDT15 gene polymorphism

测量时间点：Measure time point of outcome:

测量方法：Measure method:

指标中文名：TPMT基因多态性

测量指标：Outcomes:

指标中文名：TPMT基因多态性

Outcome: TPMT gene polymorphism

测量时间点：Measure time point of outcome:

测量方法：Measure method:

指标中文名：血常规

Outcome: Blood routine

测量时间点：Measure time point of outcome:

测量方法：Measure method:

采集人体标本：Collecting sample(s) from participants:

标本中文名：血液组织：

Sample Name: BloodTissue:

人体标本去向：使用后销毁说明

Fate of sample: Destruction after useNote:

征募研究对象情况：正在进行Recruiting

年龄范围：最小 Min age 16 岁 years最大 Max age 70 岁 years

Participant age:

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）：为非随机对照试验，不涉及随机分组

Randomization Procedure (please state who generates the random number sequence and by what method): This study is Non randomized control which does not involve random grouping.