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经自然腔道微创保胆治疗胆囊炎患者随访研究

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|----------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|----------------------------------------------------|
| 注册号: Registration number : | ChiCTR1900028267 | | |
| 最近更新日期: Date of Last Refreshed on : | 2019-12-16 | | |
| 注册时间: Date of Registration : | 2019-12-16 | | |
| 注册号状态: | 预注册 | | |
| Registration Status : | Prospective registration | | |
| 注册题目: | 经自然腔道微创保胆治疗胆囊炎患者随访研究 | | |
| Public title : | A follow-up study for cholecystitis treated with minimally invasive biliary preservation through natural cavity | | |
| 注册题目简写: | | | |
| English Acronym : | | | |
| 研究课题的正式科学名称: | 经自然腔道保胆取石治疗胆囊结石病技术创新与术后随访研究 | | |
| Scientific title : | A study for the innovation of NOTES cholelithotomy and postoperative follow-up in the treatment of cholecystolithiasis | | |
| 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: 邓立新 | 研究负责人: 张鸣青 | | |
| Applicant : Lixin Deng | Study leader : Mingqing Zhang | | |
| 申请注册联系人电话: Applicant telephone : | +86 13860835118 | 研究负责人电话: Study leader's telephone : | +86 13386966278 |
| 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 : | Lixdeng@hotmail.com | 研究负责人电子邮件: Study leader's E-mail : | zmqing8084@sina.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: | 福建省漳州市漳华中路269号内科楼 | 研究负责人通讯地址: | 福建省漳州市漳华中路269号内科楼 |
| Applicant address : | 269 Middle zhanghua Road, Zhangzhou, Fujian, China | Study leader's address : | 269 Middle zhanghua Road, Zhangzhou, Fujian, China |
| 申请注册联系人邮政编码: Applicant postcode : | 363000 | 研究负责人邮政编码: Study leader's postcode : | 363000 |
| 申请人所在单位: | 联勤保障部队第909医院 | | |
| Applicant's institution : | The 909th Hospital of the Joint Logistic Support Force | | |
| 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 : | 2018-009-01 | 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: | 中国人民解放军联勤保障部队第909医院伦理委员会 | | |
| Name of the ethic committee : | Ethics committee of The 909th Hospital of the Joint Logistic Support Force | | |
| 伦理委员会批准日期: Date of approved by ethic committee : | 2018-12-21 | | |

| | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|---------------------------------------------|--------|
| 伦理委员会联系人：郭以河 | | | |
| Contact Name of the ethic committee： | Yihe Guo | | |
| 伦理委员会联系地址：联勤保障部队第909医院 | | | |
| Contact Address of the ethic committee： | The 909th Hospital of the Joint Logistic Support Force, 269 Middle Zhanghua Road, zhangzhou, 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：联勤保障部队第909医院 | | | |
| Primary sponsor：The 909th Hospital of the Joint Logistic Support Force | | | |
| 研究实施负责（组长）单位地址：福建省漳州市漳华中路269号 | | | |
| Primary sponsor's address：269 Middle zhanghua Road, Zhangzhou, Fujian, 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)：福建 | 市(区县)： |
| | Country：China | Province：Fujian | City： |
| | 单位(医院)：联勤保障部队第909医院 | 具体地址：福建省漳州市漳华中路269号 | |
| | Institution The 909th Hospital of the hospital：Joint Logistic Support Force | Address：269 Middle Zhanghua Road, zhangzhou | |
| 经费或物资来源：2019年漳州市科技拥军项目 | | | |
| Source(s) of funding：Science and technology project of zhangzhou city for supporting the military in 2019 | | | |
| 研究疾病：胆囊结石病 | | | |
| Target disease：cholecystolithiasis | | | |
| 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：探索性研究/预试验 | | | |
| Study phase：0 | | | |
| 研究目的：1) 通过比较健康志愿者和胆囊结石患者肠道菌群的差异，探讨肠道菌群和胆囊结石形成以及相关症状的关系。2) 通过比较经肠NOTES手术患者术前术后肠道菌群的变化，探讨经肠NOTES手术对患者肠道微生态的影响。 | | | |
| Objectives of Study：1) The relationship between intestinal flora and the formation and related symptoms of cholecystolithiasis was discussed by comparing the difference of intestinal flora between healthy volunteers and patients with cholecystolithiasis; 2) The influence of transintestinal NOTES surgery on intestinal microecology of patients was discussed by comparing the changes of intestinal flora of patients undergoing transintestinal NOTES surgery before and after surgery. | | | |
| 药物成份或治疗方案详述：1) 收取确定手术患者术前、术后（一般是术后3-7天内）的粪便样品，分析经肠NOTES术对患者肠道菌群的短期影响。2) 收取健康志愿者的粪便样品，与患者术前样品测序结果对比，分析健康人群和胆结石患者肠道菌群的差异，以进一步探讨肠道菌群和胆结石形成的相关性以及与相关症状之间的关系。3) 经肠NOTES保胆取石术患者术前和术后远期（6个月、1年、2年）粪便样品菌群比较，分析患者经肠NOTES术后菌群是否重建，以及菌群变化情况，同时分析菌群变化和症状变化的关系。 | | | |
| Description for medicine or protocol of treatment in detail：1) collect feces samples before and after surgery (generally within 3-7 days after surgery) to analyze the short-term impact of transintestinal NOTES on intestinal flora of patients. 2) fecal samples from healthy volunteers were collected and compared with the sequencing results of preoperative samples from the patients. Differences in intestinal flora between healthy people and patients with gallstones were analyzed, so as to further explore the correlation between intestinal flora and gallstone formation and related symptoms. 3) compare the bacterial flora of stool samples of patients before and after biliary lithotomy (6 months, 1 year and 2 years), analyze whether the bacterial flora of patients after biliary lithotomy is reconstructed and the changes of bacterial flora, and analyze the relationship between the changes of bacterial flora and the changes of symptoms. | | | |
| 研究设计：析因分组（即根据危险因素或暴露因素分组） | | | |
| Study design：Factorial | | | |
| 纳入标准：1) 年龄30-75岁之间 2) 符合NOTES保胆取石手术指征，无其他胃肠道不适症状 3) 配合粪便样品收集工作 | | | |
| Inclusion criteria：1) between 30 and 75 years old; 2) according to the indications of NOTES gallbladder-preserving lithotomy, no other symptoms of gastrointestinal discomfort; 3) cooperate with fecal sample collection. | | | |
| 排除标准：1) 同期需要行其他胃肠道手术的患者 2) 不同意配合粪便收集工作的患者 | | | |
| Exclusion criteria：1) patients who need other gastrointestinal operations in the same period; 2) patients who do not agree to cooperate with feces collection. | | | |
| 研究实施时间： Study execute time：从2018-01-01至2023-12-31 | | | |
| 干预措施： Interventions： | 组别：对照组 | 样本量： | 50 |
| | Group：Control | Sample size： | |
| | 干预措施：无 | 干预措施代码： | |
| | Intervention：nothing | Intervention code： | |

| | | | | |
|------------------------------------------------------------|-----------------------------------------------------------------------|----------------------------------------------|-----------------------|-----------------------|
| | 组别：术前组 | | 样本量：50 | |
| | Group：Preoperative | | Sample size：50 | |
| | 干预措施：无 | | 干预措施代码： | |
| | Intervention：nothing | | Intervention code： | |
| | 组别：术后组 | | 样本量：50 | |
| | Group：Postoperative | | Sample size：50 | |
| | 干预措施：微创保胆治疗 | | 干预措施代码： | |
| | Intervention：Minimally invasive treatment with cholecyst preservation | | Intervention code： | |
| 研究实施地点： Countries of recruitment and research settings： | 国家：中国 | 省(直辖市)：福建 | 市(区县)： | |
| | Country：China | Province：Fujian | City： | |
| | 单位(医院)：909 医院 | 单位级别：三级甲等 | | |
| | Institution hospital：909th Hospital | Level of the institution：Tertiary A Hospital | | |
| | | | | |
| 测量指标： Outcomes： | 指标中文名：肠道菌群 | 指标类型：主要指标 | | |
| | Outcome：Gut microbiome | Type：Primary indicator | | |
| | 测量时间点： | 测量方法： | | |
| | Measure time point of outcome： | Measure method： | | |
| | 指标中文名：血液胆汁酸谱 | 指标类型：主要指标 | | |
| | Outcome：Serum bile acids | Type：Primary indicator | | |
| | 测量时间点： | 测量方法： | | |
| | Measure time point of outcome： | Measure method： | | |
| | 指标中文名：胆结石成分 | 指标类型：附加指标 | | |
| | Outcome：Gallstone composition | Type：Additional indicator | | |
| | 测量时间点： | 测量方法： | | |
| | Measure time point of outcome： | Measure method： | | |
| | 指标中文名：胆囊息肉病理 | 指标类型：附加指标 | | |
| | Outcome：Pathology of gallbladder polyps | 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： | | |
| | 标本中文名：胆结石/胆囊息肉 | 组织： | | |
| | Sample Name：Gallstone | Tissue： | | |
| | 人体标本去向：使用后销毁 | 说明 | | |
| | Fate of sample：Destruction after use | Note： | | |
| | 标本中文名：粪便 | 组织： | | |
| | Sample Name：Faeces | Tissue： | | |
| | 人体标本去向：使用后销毁 | 说明 | | |
| | Fate of sample：Destruction after use | Note： | | |
| | 标本中文名：尿液 | 组织： | | |
| | Sample Name：Urine | 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 30 岁 years | 最大 Max age 75 岁 years |
| 性别： Gender： | 男女均可 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）： | No, 招募健康志愿者与胆囊炎患者，两组年龄、性别等一般性基线资料相近。 |
| Randomization Procedure (please state who generates the random number sequence and by what method)： | No, Healthy volunteers and patients with cholecystitis were recruited, and the general baseline data of the two groups were similar in age, gender and other aspects. |
| 盲法： | No |
| Blinding： | No |
| 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 file)： | download |
| 原始数据公开时间： | 即时公开/Real time access |
| The time of sharing IPD： | |
| 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，需填该网络平台名称和网址）： | 2022年06月30日前在GitHub公开原始数据,网址 https://github.com/DavidWang2019/ZZ2019KD01.git |
| The way of sharing IPD"(include metadata and protocol, If use web-based public database, please provide the url)： | The public can sharing the data from GitHub before June 30, 2022 with website: https://github.com/DavidWang2019/ZZ2019KD01.git |
| 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： | 招募与随访问卷调查表，样品收集记录，医嘱、临床生化检验、影像学检查数据，肠道菌群高通量测序结果等。 |
| Data collection and Management (A standard data collection and management system include a CRF and an electronic data capture)： | Follow-up questionnaire, Sample collection record, Doctor's orders, clinical biochemical tests, imaging data, high-throughput sequencing results of intestinal flora, etc. |
| 数据管理委员会： | 暂未确定/Not yet |
| Data Managemen Committee： | |

返回列表



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