

Clinical Trial Registration Statement

Name of Journal: World Journal of Gastroenterology

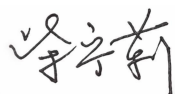
ESPS Manuscript NO: 81916

Title: Linked Color Imaging versus Lugol chromoendoscopy for esophageal squamous cell cancer and precancerous lesion screening: a noninferiority study

Authors List: Zixin Wang¹, Longsong Li¹, Song Su¹, Jinping Li¹, Bo Zhang¹, Nanjun Wang¹, Shengzhen Liu¹, Shasha Wang¹, Shuai Zhang¹, Yawei Bi¹, Fei Gao¹, Qun Shao¹, Ning Xu¹, Bozong Shao¹, Yi Yao¹, Fang Liu¹, Enqiang Linghu¹, Ningli Chai¹

1: Department of Gastroenterology, The First Medical Center of Chinese PLA General Hospital, Beijing 100853, China

Biostatistics: This study was registered in the Chinese clinical trial with the number ChiCTR2100045636 (chictr.org). A separate document was uploaded as a proof of registry.



Ningli Chai,

Department of Gastroenterology and Hepatology,
the First Medical Center of PLA General Hospital,
28 Fuxing road, Haidian District,
Beijing 100853, China

Email: chainingli@vip.163.com



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: **该项目已经通过审核, 不能再修改项目信息。**
Project audit state: This trial has been verified,you can't edit it any more.
[返回Back](#)

注册号:
Registration number: ChiCTR2100045636

最近更新日期:
Date of Last Refreshed on: 2021/12/6 8:50:28

注册号状态: 预注册

Registration Status: 1008001 Prospective registration

注册题目: 联动成像技术和碘染色在诊断食管早癌及癌前病变中的应用与对比

Public title: Linked color imaging versus lugol chromoendoscopy for screening of esophageal squamous cell neoplasia and precancerous lesions

研究课题的正式科学名称: 联动成像技术和碘染色在诊断食管早癌及癌前病变中的应用与对比

Scientific title: Linked color imaging versus lugol chromoendoscopy for screening of esophageal squamous cell neoplasia and precancerous lesions

| | |
|---|--|
| 研究课题代号(代码): Study subject ID: | |
| 在其它机构的注册号: Secondary ID: | |
| <hr/> | |
| 申请注册联系人: 王子鑫 | 研究负责人: 柴宁莉 |
| Applicant: Wang Zixin | Study leader: Chai Ningli |
| 申请注册联系人电话: Applicant telephone: +86 18560789821 | 研究负责人电话: Study leader's telephone: +86 15011362982 |
| 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: wzxruby@163.com | 研究负责人电子邮件: Study leader's E-mail: chainingli@vip.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: 北京市海淀区复兴路28号 | 研究负责人通讯地址: 北京市海淀区复兴路28号 |
| Applicant address: 28 Fuxing Road, Haidian District, Beijing | Study leader's address: 28 Fuxing Road, Haidian District, Beijing |
| 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: 中国人民解放军总医院 | |
| Applicant's institution: The General Hospital of the People's Liberation Army | |
| <hr/> | |
| 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: S2012-145-01 | 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: 中国人民解放军总医院伦理委员会 | |
| Name of the ethic committee: Chinese People's Liberation Army General Hospital Ethics Committee | |

| | | | | | |
|--|--|-----------------------|--|---|----------------------------------|
| 伦理委员会批准日期: Date of approved by ethic committee: | | | | 2021/03/25 | |
| 伦理委员会联系人: 白楠 | | | | | |
| Contact Name of the ethic committee: | | | | Bai Nan | |
| 伦理委员会联系地址: 北京市海淀区道复兴路28号 | | | | | |
| Contact Address of the ethic committee: | | | | 28 Fuxing Road, Haidian District, Beijing | |
| 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: 中国人民解放军总医院 | | | | | |
| Primary sponsor: | | | | The General Hospital of the People's Liberation Army | |
| 研究实施负责(组长)单位地址: 北京市海淀区复兴路28号 | | | | | |
| Primary sponsor's address: | | | | 28 Fuxing Road, Haidian District, Beijing | |
| 试验主办单位(项目批准或申办者): Secondary sponsor: | | 国家: | 中国 | 省(直辖市): | 北京 |
| | | Country: | China | Province: | Beijing |
| | | 市(区县): | | | |
| | | City: | | | |
| | | 单位(医院): | 中国人民解放军总医院 | 具体地址: | 海淀区复兴路28号 |
| | | Institution hospital: | The General Hospital of the People's Liberation Army | Address: | 28 Fuxing Road, Haidian District |
| 经费或物资来源: 无 | | | | | |
| Source(s) of funding: | | | | self-funded | |
| 研究疾病: 食管早癌及癌前病变 | | | | | |
| Target disease: | | | | esophageal squamous cell neoplasia and precancerous lesions | |
| 研究疾病代码: | | | | | |

| | |
|----------------------|--|
| Target disease code: | |
| 研究类型: | 诊断试验 |
| Study type: | Diagnostic test |
| 研究所处阶段: | 探索性研究/预试验 |
| Study phase: | 0 |
| 研究目的: | 分析比较联动成像技术和碘染色对于食管早癌及癌前病变的诊断效能是否存在差异，是否能用联动成像技术和碘染色用于诊断食管肿瘤性病变（食管鳞癌，不典型增生）。 |
| Objectives of Study: | To analyze and compare the differences of diagnostic efficacy between linked color imaging and Lugol staining for early esophageal cancer and precancerous lesions, and whether linked color imaging can be used to replace Lugol staining in the diagnosis of esophageal neoplastic lesions (esophageal squamous cell carcinoma, atypical hyperplasia). |
| 研究设计: | 连续入组 |
| Study design: | Sequential |
| 纳入标准: | 1.来我院行胃镜筛查者，年45-85岁； 2.签署知情同意书。 |
| Inclusion criteria | 1. Patient who were 45-85 years required endoscopic examination; 2. Agree to participate in this research activity and sign an informed consent. |
| 排除标准: | 1.对卢戈尔染色内镜不耐受/碘过敏/甲亢患者； 2.内镜检查 禁忌； 3.麻醉禁忌； 4.禁止停止抗血小板或抗凝药物； 5.食管癌曾接受过 手术切除、化疗、放疗的患者。 |
| Exclusion criteria: | 1. Patients with intolerance to Lugol staining endoscopy/iodine allergy/hyperthyroidism; 2. Endoscopy is taboo; 3. Anesthesia taboo; 4. It is forbidden to stop antiplatelet or anticoagulant drugs; 5. Patients with esophageal cancer who have received surgical resection, chemotherapy, and radiotherapy. |
| 研究实施时间: | 从2021/04/30至2022/09/30 |
| Study execute time: | |

金标准或参考标准（即可准确诊断某疾病的单项方法或多项联合方法，在本研究中用于诊断是否有该病的临床参考标准）：

活检后的病理结果

Gold Standard or Reference Standard (The clinical reference standards required to establish the presence or absence of the target condition in the tested population in present study):

Pathological results

指标试验（即本研究的待评估诊断试验，无论

| | | |
|----------------------------|---|---|
| 诊断试验: Diagnostic Tests: | 为方法、生物标志物或设备, 均请列出名称): | 联动成像技术 |
| | Index test: | Linked Color Imaging |
| | 目标人群 (可以是某种疾病患者或正常人群, 详细描述其疾病特征, 注意应纳入符合分布特点的全序列病例, 具有良好的代表性) | 有上消化道不适的人群 |
| | Target condition (The target condition is a particular disease or disease stage that the index test will be intended to identify. Please specify the characteristics in detail; the population should has a complete spectrum and good representative): | Patients with upper Digestive symptoms. |
| | 容易混淆的疾病人群 (即与目标疾病不易区分的一种或多种不同疾病, 应避免采用正常人群对照的病例-对照设计): | |
| | Population with condition difficult to distinguish from the target condition, the normal population in a case-control study design should be avoid: | |
| | | 例数: Sample size: 0 |
| | | 例数: Sample size: 0 |

| | | | | | |
|--|-----------------------|--|---------------------------|------------|--------|
| 研究实施地点: Countries of recruitment and research settings: | 国家: | 中国 | 省(直辖市): | 北京 | 市(区县): |
| | Country: | China | Province: | Beijing | City: |
| | 单位(医院): | 中国人民解放军总医院 | 单位级别: | 三级甲等 | |
| | Institution hospital: | The General Hospital of the People's Liberation Army | Level of the institution: | Tertiary A | |

| | |
|----------|-------------|
| 指标中文名: | 灵敏度 |
| Outcome: | Sensitivity |

| | |
|--------------------------------|-----------------|
| Measure time point of outcome: | Measure method: |
| 指标中文名: 特异度 | |
| Outcome: Specificity | |
| 测量时间点: | 测量方法: |
| Measure time point of outcome: | Measure method: |

| | |
|---|-----------------|
| 指标中文名: 食管早癌/癌前病变检出率 | |
| Outcome: Detection rate of early esophageal cancer/precancerous lesions | |
| 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: 黏膜 | | 组织: 食管 | |
| | Sample Name: mucosa | | Tissue: esophagus | |
| | 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: | 正在进行 Recruiting | 年龄范围: Participant age: | 最小 Min age | 45 | 岁 years |
| | | | 最大 Max age | 85 | 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): 无

| | |
|---|--|
| Randomization Procedure (please state who generates the random number sequence and by what method): | None |
| 盲法: | 未说明 |
| Blinding: | Not stated |
| 是否公开试验完成后的统计结果: Calculated Results ater the Study Completed public access: | <div>公开/Public</div> <div>变更change</div> |
| 上传的试验完成后的统计结果: Statistical results after completion of the test file upload: | <div>重传Upload:</div> <div><div>选择文件</div><div>未选择文件</div></div> <div>*</div> |
| UTN(全球唯一识别码): | |
| 是否共享原始数据: IPD sharing | 是Yes |
| 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) : | 论文发表形式 请阅读网页注册指南中 关于 原始数据共享的内容。 |
| The way of sharing IPD”(include metadata and protocol, If use web-based public database, please provide the url): | paper publication. |
| 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。: | 应用EXCEL建立数据库保存病例原始资料。 |
| Data collection and Management (A standard data collection and management system include a CRF and an electronic data capture : | Using EXCEL to bulid a data base to management the orginal data. |

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

研究计划书或研究结果报告发表信息
(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):

修改/update

注册人:
Name of Registration: 2021/04/20

项目来源:
Project Origin: 本站

返回Back