

北京军区总医院伦理委员会快速审批件

编号：2016-045

项目 名称	Cronkhite-Canada 综合征息肉并 IgG4 阳性浆细胞浸润 Cronkhite-Canada syndrome polyps infiltrated with IgG4-positive plasma cells		
类别	1. 器官移植 ()； 2. 新业务新技术 ()； 3. 辅助生殖 ()； 4. 临床试验 ()； 5. 医学研究 (√)		
科室	消化内科 Department of Gastroenterology	项目负责人	范如英(Ru-Ying Fan)
材料 内容	<p>我院收住 1 位 Cronkhite-Canada 综合症患者，它表现为胃肠多发息肉，腹泻，并有指甲萎缩、脱发等外胚层表现，为罕见病例。拟征得患者的同意后采集其病史并发表，该研究无任何健康及经济风险并保证患者的隐私权。</p> <p>Cronkhite-Canada syndrome (CCS) is a rare condition characterized by gastrointestinal polyposis associated with diarrhea and epidermal manifestations, such as cutaneous hyperpigmentation, alopecia and onychodystrophy. we will collect patient's medical records and published it in journal. This study did not bring adverse effect to patient's health and no pay more money for this study. The patient's privacy will be protected.</p>		
<p>依据 GCP 要求及相关法规，本伦理委员会的组织和实施相对独立 本院伦理委员会的人员组成和工作程序符合 GCP 原则及国家相关规定 The ethics committee's responsibilities, composition, function, operations and records are fully compliant with ICH-GCP, and related regulation and law of China</p>			
<p>本项目已经通过北京军区总医院伦理审查（编号 2016-045），请严格按照北京军区总医院伦理审查意见和实验方案进行。如有修改，须报我院伦理委员会审查。 The study protocol was in accordance with the declaration of Helsinki, it was reviewed and approved by the Beijing Military General Hospital Institutional Review Board. The approval number was 2016-045</p>			
<p>伦理委员会审批意见：</p> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="width: 40%;">  </div> <div style="width: 55%; text-align: right;"> <p>主任委员签名： </p> <p>北京军区总医院伦理委员会</p> <p>2016 年 02 月 05 日</p> </div> </div>			