

上海交通大学医学院附属新华医院医学伦理委员会

Shanghai Jiao tong University Xinhua Hospital Ethics Committee

审批号 XHEC-D-2011-016

关于“The comparison between air and carbon dioxide insufflation in the endoscopic submucosal excavation of gastrointestinal stromal tumors” 伦理评审意见

王子豪、施伟斌、徐雷鸣等医师进行的“The comparison between air and carbon dioxide insufflation in the endoscopic submucosal excavation of gastrointestinal stromal tumors”研究是一个临床前瞻性研究，研究目的是评价在内镜黏膜下挖除术治疗胃肠道间质瘤中应用二氧化碳（CO₂）的安全性与有效性。

伦理委员会已经评估了本研究的设计，执行过程并已阅读了文章，认为此研究为临床前瞻性研究，所有研究对象随机分为两组，分别注入 CO₂ 或空气进行 ESE 操作治疗。此研究未采用任何可识别病人身份的标本和数据，研究者严格遵循《赫尔辛基宣言》的伦理准则。

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2011 年 02 月 08 日



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The Ethical Review on the Clinical Research of “The comparison between air and carbon dioxide insufflation in the endoscopic submucosal excavation of gastrointestinal stromal tumors”

The clinical research of “The comparison between air and carbon dioxide insufflation in the endoscopic submucosal excavation of gastrointestinal stromal tumors”, which was conducted by Doctor Zihao Wang et al, aimed at evaluate the safety and efficacy of CO₂ insufflation in the endoscopic submucosal excavation of gastrointestinal stromal tumors.

We have reviewed the study design and process as well as the manuscript. We certify that this study was an observational study and the endoscopic submucosal excavation (ESE) was a regular surgical operation, so it was safe for patients. We certify that this study did not raise any issue of patient's risk and did not use identifiable human material or data. We also certify that the study was in accordance with the Declaration of Helsinki and that the study was conducted without ethics problems.

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2011-02-08



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