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|---|---|---------------------------------------|---|--|-------|
| 注册号: Registration number: | ChiCTR1900020630 | | | | |
| 最近更新日期: Date of Last Refreshed on: | 2019/1/11 6:22:28 | | | | |
| 注册号状态: | 补注册 | | | | |
| Registration Status: | 1008002 Retrospective registration | | | | |
| 注册题目: | 罗哌卡因局部浸润麻醉在肝胆手术后镇痛及ERAS的应用 | | | | |
| Public title: | The effect of local infiltration of ropivacaine in postoperative pain and ERAS | | | | |
| 研究课题的正式科学名称: | 罗哌卡因局部浸润麻醉在肝胆手术后镇痛及ERAS的应用 | | | | |
| Scientific title: | The effect of local infiltration of ropivacaine in postoperative pain and ERAS | | | | |
| 研究课题代号(代码): Study subject ID: | 国家自然科学基金 (No. 81571367) ; 山东省科技攻关项目 (No.2017GSF218021) | | | | |
| 在其它机构的注册号: Secondary ID: | | | | | |
| 申请注册联系人: | 张浩 | 研究负责人: | 靳斌 | | |
| Applicant: | Hao Zhang | Study leader: | Bin Jin | | |
| 申请注册联系人电话: Applicant telephone: | +86 18366116329 | 研究负责人电话: Study leader's telephone: | +86 18560085136 | | |
| 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: | zhanghao370123@163.com | | 研究负责人电子邮件: Study leader's E-mail: | jinbin9449@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: | 山东省济南市历下区文化西路107号 | | 研究负责人通讯地址: | 山东省济南市历下区文化西路107号 | |
| Applicant address: | 107 Wenhua Road West, Lixia, Ji'nan, Shandong, China | | Study leader's address: | 107 Wenhua Road West, Lixia, Ji'nan, Shandong, China | |
| 申请注册联系人邮政编码: Applicant postcode: | 250012 | | 研究负责人邮政编码: Study leader's postcode: | 250012 | |
| 申请人所在单位: | 山东大学齐鲁医院 | | | | |
| Applicant's institution: | Department of general Surgery, Qilu Hospital of Shandong University, Jinan, China | | | | |
| 是否获伦理委员会批准: | 是 | | | | |
| Approved by ethic committee: | Yes | | | | |
| 伦理委员会批准文号: Approved No. of ethic committee: | 2017052 | | 伦理委员会批准附件: | 查看附件View | |
| 批准本研究的伦理委员会名称: | 山东大学齐鲁医院伦理委员会 | | | | |
| Name of the ethic committee: | the ethics committee of Qilu Hospital of Shandong University | | | | |
| 伦理委员会批准日期: Date of approved by ethic committee: | 2017/06/26 | | | | |
| 伦理委员会联系人: | 李延青 | | | | |
| Contact Name of the ethic committee: | YanQing Li | | | | |
| 伦理委员会联系地址: | 山东省济南市历下区文化西路107号 | | | | |
| Contact Address of the ethic committee: | Qilu Hospital of Shandong University, 107 Wenhua Road West, Lixia, Ji'nan, Shandong, 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: | 山东大学齐鲁医院 | | | | |
| Primary sponsor: | Qilu Hospital of Shandong University | | | | |
| 研究实施负责 (组长) 单位地址: | 山东省济南市历下区文化西路107号 | | | | |
| Primary sponsor's address: | 107 Wenhua Road West, Lixia, Ji'nan, Shandong, China | | | | |
| 国家: | 中国 | 省(直辖市): | 山东省 | 市(区县): | 济南市 |
| Country: | China | Province: | Shandong | City: | Jinan |
| 试验主办单位(项目批准或申办者): Secondary sponsor: | 单位(医院): | 山东大学齐鲁医院 | 具体地址: | 山东省济南市历下区文化西路107号 | |
| Institution hospital: | Qilu Hospital of Shandong University, Jinan, China | Address: | 107 Wenhua Road West, Lixia, Ji'nan, Shandong, China | | |
| 经费或物资来源: | 国家自然科学基金 (No. 81571367) ; 山东省科技攻关项目 (No.2017GSF218021) | | | | |
| Source(s) of funding: | National Natural Science Foundation of China (No. 81571367), Technological Project of Shandong Province (No.2017GSF218021) | | | | |
| 研究疾病: | 术后疼痛 | | | | |
| Target disease: | pain after surgery | | | | |
| 研究疾病代码: | | | | | |
| Target disease code: | | | | | |
| 研究类型: | 干预性研究 | | | | |
| Study type: | Interventional study | | | | |
| 研究所处阶段: | 其它 | | | | |
| Study phase: | N/A | | | | |
| 研究目的: | 通过对肝胆外科手术术后使用罗哌卡因与不使用罗哌卡因进行局部浸润麻醉的患者的疼痛评分、平均动脉压、恶心呕吐的症状、血清指标等反应疼痛程度的指标进行对比, 旨在了解罗哌卡因局部浸润麻醉对于肝胆手术后疼痛程度的影响, 从而为罗哌卡因在术后的临床应用提供一定的依据。 | | | | |

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| Objectives of Study: | The main purpose of this study was to evaluate the effects of ropivacaine on pain control after laparoscopic hepatectomy. The second purpose was to examine whether this local anesthetic technique accelerates patient recovery, thus contributing to the idea of fast track recovery surgery. |
| 研究设计: | 随机平行对照 |
| Study design: | Parallel |
| 纳入标准: | (1) 均为检查确诊的肝脏疾病、慢性胆囊炎或胆结石需行肝胆外科手术的患者; (2) 性别不限, 年龄20-80岁, 体重50-80kg。 (3) 实验组患者于手术结束时行罗哌卡因局部浸润麻醉, 对照组行同部位、同剂量生理盐水浸润注射。 |
| Inclusion criteria: | 1. patients need accept surgery because of the hepatobiliary diseases; 2. Male and female aged 20-80 years, weight 50-80 kg; 3. the experiment group accept the infiltration of ropivacaine, the same in control group with normal saline solution. |
| 排除标准: | 1.急性胆囊炎 2.患有除肝胆疾病以外的慢性疼痛疾病 3.长期酗酒者 4.术前1天内接受镇痛治疗者 5.认知障碍者 6.严重肝病患者 7. 手术时间超过120min |
| Exclusion criteria: | Patients were excluded if they had acute cholecystitis, serious chronic pain disease, history of alcohol abuse, tranquilizer treatment before surgery, cognitive impairment, or history of allergy to any of the drugs used in the study. |
| 研究实施时间: | 从From2017/07/01至To 2018/09/30 |
| Study execute time: | |

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| 干预措施: Interventions: | 组别: | 罗哌卡因组 | 样本量: | 100 |
| | Group: | Group 1 | Sample size: | |
| | 干预措施: | 罗哌卡因 | 干预措施代码: | |
| | Intervention: | 罗哌卡因组 | Intervention code: | |
| | 组别: | 对照组 | 样本量: | 100 |
| | Group: | Group 2 | Sample size: | |
| | 干预措施: | 生理盐水 | 干预措施代码: | |
| | Intervention: | 对照组 | Intervention code: | |

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| 研究实施地点: Countries of recruitment and research settings: | 国家: | 中国 | 省(直辖市): | 山东省 | 市(区县): | 济南市 |
| | Country: | China | Province: | Shandong | City: | Jinan |
| | 单位(医院): | 山东大学齐鲁医院 | 单位级别: | 三甲医院 | | |
| | Institution hospital: | Qilu Hospital of Shandong University, Jinan, China | Level of the institution: | Tertiary A Hospital | | |

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| 测量指标: Outcomes: | 指标中文名: | 视觉模拟评分法 | |
| | Outcome: | VAS | |
| | 测量时间点: | 术后0 6 12 24 48小时 | 测量方法: |
| | Measure time point of outcome: | 0, 6, 12, 24, 48 hours postoperation | Measure method: |
| | 指标中文名: | 心率 | |
| | Outcome: | Heart rate | |
| | 测量时间点: | | 测量方法: |
| | Measure time point of outcome: | | Measure method: |
| | 指标中文名: | 平均动脉压 | |
| | Outcome: | MAP | |
| | 测量时间点: | | 测量方法: |
| | Measure time point of outcome: | | Measure method: |
| | 指标中文名: | 肾上腺素 | |
| | Outcome: | epinephrine | |
| | 测量时间点: | | 测量方法: |
| | Measure time point of outcome: | | Measure method: |
| | 指标中文名: | 去甲肾上腺素 | |
| | Outcome: | norepinephrine | |
| | 测量时间点: | | 测量方法: |
| | Measure time point of outcome: | | Measure method: |
| | 指标中文名: | 麻醉药物用量 | |
| | Outcome: | accumulate of sufentanil | |
| | 测量时间点: | | 测量方法: |
| | Measure time point of outcome: | | Measure method: |

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| 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: |

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| 征募研究对象情况: | 结束 | 年龄范围: | 最小 Min age 20 岁 years |
| Recruiting status: | Completed | Participant age: | 最大 Max age 80 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): 新斌 随机数表法 | | | |

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| Randomization Procedure (please state who generates the random number sequence and by what method): | Random number table by Jin Bin |
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