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审核状态:

Project audit state:

该项目已经通过审核, 不能再修改项目信息。

This trial has been verified,you can't edit it any more.

返回Back

注册号:  
Registration number:

ChiCTR2100053744

最近更新日期:  
Date of Last Refreshed on:

2021/11/28 10:37:51

注册号状态:

补注册

Registration Status:

1008002 Retrospective registration

注册题目:

G型入路机器人辅助胰十二指肠联合切除术治疗壶腹部肿瘤的临床疗效分析

Public title:

Clinical analysis of G-type robot assisted pancreaticoduodenectomy in the treatment of ampullary tumors

研究课题的正式科学名称:

G型入路机器人辅助胰十二指肠联合切除术治疗壶腹部肿瘤的临床疗效分析

Scientific title:

Clinical analysis of G-type robot assisted pancreaticoduodenectomy in the treatment of ampullary tumors

研究课题代号(代码):  
Study subject ID:

在其它机构的注册号:  
Secondary ID:

申请注册联系人:  
Applicant:

霍天宇  
Tian-Yu Huo

研究负责人:  
Study leader:

魏志刚  
Zhi-Gnag Wei

申请注册联系人电话:  
Applicant telephone:

研究负责人电话:  
Study leader's telephone:

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:

1440026990@qq.com

研究负责人电子邮件:  
Study leader's E-mail:

wzgsyyy@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:

山西省太原市解放南路85号

研究负责人通讯地址:

山西省太原市解放南路85号

Applicant address:

85 South Jiefang Road, Taiyuan, Shanxi, China

Study leader's address:

85 South Jiefang Road, Taiyuan, Shanxi, China

申请注册联系人邮政编码:

研究负责人邮政编码:

申请人所在单位:

山西医科大学第一医院

Applicant's institution:

The First Hospital of Shanxi Medical University

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:

[2019]伦审字 (SK013) 号

伦理委员会批件附件:

查看附件View

批准本研究的伦理委员会名称:

山西医科大学第一医院医学伦理委员会

Name of the ethic committee:

Medical ethics committee of the first hospital of Shanxi Medical University

伦理委员会批准日期:  
Date of approved by ethic committee:

2019/07/26

伦理委员会联系人:

李拥军

Contact Name of the ethic committee:

Yong-Jun Li

伦理委员会联系地址:

山西省太原市解放南路85号

Contact Address of the ethic committee:

85 South Jiefang Road, Taiyuan, Shanxi, 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:

山西医科大学第一医院

Primary sponsor:

The first hospital of Shanxi Medical University

研究实施负责 (组长) 单位地址:

山西省太原市解放南路85号

Primary sponsor's address:

85 South Jiefang Road, Taiyuan, Shanxi, 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):

山西

市(区县):

Country:

China

Province:

Shanxi

City:

单位(医院):

山西医科大学第一医院

具体地址:

山西省太原市解放南路85号

Institution hospital:

The first hospital of Shanxi Medical University

Address:

No. 85, Jiefang South Road, Taiyuan, Shanxi

经费或物资来源:

山西省重点研发计划项目

Source(s) of funding:

Key research and development projects in Shanxi Province

研究疾病:

壶腹部肿瘤

Target disease:

Ampullary tumor

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:

本研究将通过随机对照实验明确G型入路机器人胰十二指肠切除术治疗壶腹部肿瘤的安全性、可行性和中、远期疗效, 3年内连续纳入100例符合壶腹部肿瘤患者, 随机分入G型入路机器人胰十二指肠切除术(实验组)与开腹胰十二指肠切除术, 对两组病人的术中、术后、以及病理参数、免疫功能、1、3年生存期等指标进行比较, 初步明确G型入路机器人胰十二指肠切除术治疗壶腹部肿瘤的安全性和疗效以及其学习曲线、为手术治疗壶腹部肿瘤提供循证医学证据。

Objectives of Study:

In this study, the safety, feasibility, medium-term and long-term efficacy of G-type robotic pancreaticoduodenectomy in the treatment of ampullary tumors will be determined through a randomized controlled experiment. 100 patients who meet the requirements of ampullary tumors will be included within 3 years. They will be randomly divided into G-type robotic pancreaticoduodenectomy (experimental group) and open pancreaticoduodenectomy And pathological parameters, immune function, 1-year and 3-year survival, to preliminarily clarify the safety, efficacy and learning curve of G-type robotic pancreaticoduodenectomy in the treatment of ampullary tumors, so as to provide evidence-based medical evidence for the surgical treatment of ampullary tumors.

研究设计:

随机平行对照

Study design:

Parallel

纳入标准:

①有明确的病理确诊为壶腹部肿瘤, 即癌组织浸润到粘膜下层, 进入肌层或已穿过肌层达浆膜(T1b或T1b以上, N0或N0以上); ②术前B超及CT检查无远处脏器转移(M0); ③术前血常规、血型、凝血功能、肝肾功能(生化全项)及感染筛查等检查未见异常, 且肿瘤标志物(CEA、CA199、CA72.4、CA242)检测完善; ④肿瘤原发灶能够R0切除; ⑤无其他重要相关疾病(例如其他恶性肿瘤, 严重心脏和中枢神经系统疾病等); ⑥Karnofsky评分≥70; ⑦年龄大于18周岁; ⑧意识清楚, 能理解并清晰回答问题; ⑨签署知情同意书

Inclusion criteria

1. There is a definite pathological diagnosis of ampullary tumor, that is, the cancer tissue infiltrates into the submucosa, enters the muscular layer or has passed through the muscular layer to the serosa (T1b or above, N0 or above); 2. There was no distant organ metastasis (M0) by B-ultrasound and CT before operation; 3. No abnormality was found in preoperative blood routine, blood type, coagulation function, liver and kidney function (biochemical items) and infection screening, and the detection of tumor markers (CEA, CA199, ca72.4 and CA242) was perfect; 4. The primary tumor can be resected by R0; 5. No other important related diseases (such as other malignant tumors, serious heart and central nervous system diseases, etc.); 6. Karnofsky score >=70; 7. Older than 18 years old; 8. Be conscious, able to understand and answer questions clearly; 9. Sign informed consent.

排除标准:

①一般情况不能耐受手术; ②伴远处转移; ③肿瘤直径>10cm; ④淋巴结转移灶融合并包绕重要血管和(或)肿瘤与周围组织器官广泛浸润。⑤已实施新辅助治疗或推荐新辅助治疗的壶腹部肿瘤患者。

Exclusion criteria:

1. The basic status not tolerates the operation; 2. With distant metastasis; 3. Tumor diameter > 10 cm; 4. Lymph node metastases fuse and surround important blood vessels and / or tumor and surrounding tissues and organs. 5. Patients with ampullary tumors who have implemented neoadjuvant therapy or recommended neoadjuvant therapy.

研究实施时间:  
Study execute time:

从From:2019/07/01至To:2022/07/31

组别:

机器人辅助治疗组

样本量:

50

Group:

Robot assisted therapy group

Sample size:

50

干预措施:

机器人辅助治疗

干预措施代码:

Intervention:

机器人辅助治疗组

Intervention code:

组别:

开腹治疗组

样本量:

50

Group:

Laparotomy treatment group

Sample size:

50

干预措施:

开腹治疗

干预措施代码:

Intervention:

开腹治疗组

Intervention code:

研究实施地点:  
Countries of recruitment and research settings:

国家:

中国

省(直辖市):

山西

市(区县):

Country:

China

Province:

Shanxi

City:

单位(医院):

山西医科大学第一医院

单位级别:

三级甲等医院

Institution hospital:

The first hospital of Shanxi Medical University

Level of the institution:

Tertiary A Hospital

指标中文名:

影像学检查

Outcome:

radiological examination

测量时间点:

Measure time point of outcome:

测量方法:

Measure method:

指标中文名:

血清肿瘤标志物

Outcome:

Serum tumor markers

测量时间点:

Measure time point of outcome:

测量方法:

Measure method:

指标中文名:

生存状况

Outcome:

living conditions

测量时间点:

Measure time point of outcome:

测量方法:

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:

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 岁 years  
最大 Max age 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):

区组随机化分组

Randomization Procedure (please state who generates the random number sequence and by what method):

Block randomization

盲法:

Open label

Blinding:

Open label

是否公开试验完成后的统计结果:  
Calculated Results ater the Study Completed public access:

不公开/Private ▾ 变更change

上传的试验完成后的统计结果:  
Statistical results after completion of the test file upload:

重传Upload: 选择文件 未选择任何文件 \*

UTN(全球唯一识别码):

是否共享原始数据:  
IPD sharing

否No

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):

ResMan

The way of sharing IPD\*(include metadata and protocol, If use web-based public database, please provide the url):

ResMan

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。:

电子采集和管理系统

Data collection and Management (A standard data collection and management system include a CRF and an electronic data capture:

Electronic Data Capture

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:

2021/11/28

项目来源: