



检索试验

按国家、省
(市) 统计按疾病代码统
计按试验实施单
位统计按试验主办单
位统计按经费或物资
来源统计按征募研究对
象情况统计按注册状态统
计按干预措施统
计按伦理委员会
统计按研究类型统
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新辅助放化疗联合手术治疗潜在可手术胸段食管鳞癌的临床研究

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注册号:
Registration number: ChiCTR-OIC-17011648最近更新日期:
Date of Last Refreshed on: 2017-06-13注册时间:
Date of Registration: 2017-06-13

注册号状态: 补注册

Registration Status: Retrospective registration

注册题目: 新辅助放化疗联合手术治疗潜在可手术胸段食管鳞癌的临床研究

Public title: Neoadjuvant chemoradiotherapy combined with surgery in the treatment of potentially operable thoracic squamous cell carcinoma of the esophagus

注册题目简写:

English Acronym:

研究课题的正式科学名称: 新辅助放化疗联合手术治疗潜在可手术胸段食管鳞癌的临床研究

Scientific title: Neoadjuvant chemoradiotherapy combined with surgery in the treatment of potentially operable thoracic squamous cell carcinoma of the esophagus

研究课题代号(代码):
Study subject ID:在二级注册机构或其它机构的注册
号:
The registration number of the
Partner Registry or other
register:

申请注册联系人: 闫茂慧

研究负责人: 刘芳

Applicant: Yan Maohui

Study leader: Liu Fang

申请注册联系人电话:
Applicant telephone: +86 18301071600研究负责人电话:
Study leader's telephone: +86 13520469875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: 357278864@qq.com研究负责人电子邮件:
Study leader's E-mail: liufangfsg@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 中国人民解放军总医院

研究负责人通讯地址: 北京市海淀区复兴路28号 中国人民解放军总医院

Applicant address: 28 Fuxing Road, Haidian District, Beijing, China

Study leader's address: 28 Fuxing Road, Haidian District, Beijing, China

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: General Hospital of PLA medical

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:

伦理委员会批件附件:

Approved No. of ethic committee: S2017-001-02		Approved file of Ethical Committee:			
批准本研究的伦理委员会名称:		中国人民解放军总医院医学伦理委员会			
Name of the ethic committee:		General Hospital of PLA medical ethics committee			
伦理委员会批准日期: Date of approved by ethic committee:					
伦理委员会联系人:					
Contact Name of the ethic committee:					
伦理委员会联系地址:					
Contact Address of the ethic committee:					
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:		Chinese PLA General Hospital			
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, 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):	北京市	市(区县):
	Country:	China	Province:	Beijing	City:
	单位(医院):	中国人民解放军总医院	具体地址:	北京市海淀区复兴路28号 解放军总医院	
	Institution hospital:	Chinese PLA General Hospital	Address:	28 Fuxing Road, Haidian District, Beijing, China	
经费或物资来源:		自筹			
Source(s) of funding:		self-financing			
研究疾病:		食管癌			
Target disease:		esophageal cancer			
研究疾病代码:					
Target disease code:					
研究类型:		观察性研究			
Study type:		Observational study			
研究所处阶段:		II期临床试验			
Study phase:		2			
研究目的:		评价新辅助放化疗联合手术治疗潜在可手术胸段食管鳞癌的有效性及安全性			
Objectives of Study:		To evaluate the efficacy and safety of neoadjuvant chemoradiotherapy combined with surgery in the treatment of potentially operable thoracic squamous cell carcinoma of the esophagus			
药物成份或治疗方案详述:					
Description for medicine or protocol of treatment in detail:					
研究设计:		单臂			
Study design:		Single arm			
纳入标准:		1. 经病理学证实为鳞癌的胸段食管恶性肿瘤 2. 治疗前临床分期为局部晚期(T3-4N0-1M0)或局部早期伴区域淋巴结转移(T1-2N1M0) 3. 预计生存期大于 6 个月 4. 年龄 18~65 岁,KPS 评分>80(KPS 评分标准详见附件 1) 5. 实验室化验指标必须符合下列要求: 血常规:白细胞≥4.0x109/L、中性粒细胞≥1.5x109/L、血小板计数≥100x109/L、 血红蛋白≥90g/L; 肝肾功能:血清胆红素低于最大正常值的 1.5 倍;ALT 和 AST 低于最大正常值 的 1.5 倍;BUN、Cr 在正常范围之内 6. 患者既往未接受过正规的抗肿瘤治疗 7. 能理解本研究的情况并签署知情同意书			
Inclusion criteria		1. Malignant neoplasm of thoracic esophagus proved by pathology to be squamous cell carcinoma 2. Clinical staging before treatment is locally advanced (T3-4N0-1M0) or locally early with regional lymph node metastasis (T1-2N1M0); 3. expect survival longer than 6 months; 4. Aged 18~65 years old, KPS score >80 (KPS standard, see Appendix 1); 5. Laboratory test indicators must meet the following requirements: Blood: white blood cells than 4.0x10^9/L, neutrophils or 1.5x10^9/L, platelet count, hemoglobin 90g/L or more than 100x10^9/L; Liver and kidney function: serum bilirubin is lower than the maximum normal value of 1.5 times; ALT and AST are lower than the maximum normal value of 1.5 times; BUN and Cr are within the normal range; 6. Patients who have not received formal anti-tumor therapy; 7. Be able to understand the situation of this study and sign informed consent.			

排除标准:	1. 治疗前临床分期 T4,突破食管外膜侵及周围组织,有食管穿孔高危因素 已行抗肿瘤治疗(包括化疗、放疗、手术) 2.已知或怀疑对化疗药物紫杉醇、洛铂等过敏者 3.已经存在或合并存在出血性疾病者 4.其他不可控制的不可手术患者 5.妊娠、哺乳期患者 6.心理、家庭、社会等因素导致不知情同意者 7.由于以往手术导致本次手术不能应用胃代食管重建消化道者 8.存在末梢神经病变患者,CTC 分级≥2 级 9.入组前除食管癌外有其他恶性肿瘤病史的患者,非黑色素瘤的皮肤癌、原位宫颈癌除外 10.研究者认为不宜参加本研究者 11.有严重心、肺、肝、肾功能不全、造血系统疾病、免疫系统疾病、恶病质等不可耐受手术的患者						
Exclusion criteria:	1. the clinical stage before treatment T4, breaking through the esophageal adventitia invasion and surrounding tissue, esophageal perforation high-risk factors have been anti-tumor treatment (including chemotherapy, radiotherapy, surgery); 2. known or suspected of chemotherapy drugs such as paclitaxel, platinum, platinum and other allergies; 3. having or merging with hemorrhagic disease; 4. other non controllable non operable patients; 5. pregnant and lactating patients; 6. psychological, family, social and other factors lead to the absence of informed consent; 7. because of previous surgery, this operation can not be used for gastric reconstruction of the digestive tract; 8. patients with peripheral neuropathy, CTC grade level is more than 2; 9. patients with a history of other malignancies except those with esophageal cancer, except for non melanoma skin cancer and in situ cervical cancer; 10. the researchers considered unsuitable to participate in this study; 11. there are serious heart, lung, liver and kidney dysfunction, hematopoietic diseases, immune system diseases, cachexia and other intolerance surgery patients.						
研究实施时间: Study execute time:	从From2016-11-01至To 2018-11-01			征募观察对象时间: Recruiting time:	从From2016-11-01至To 2020-11-01		
干预措施: Interventions:	组别:	试验组			样本量:	34	
	Group:	experimental group			Sample size:		
	干预措施:	新辅助放化疗			干预措施代码:		
	Intervention:	Neoadjuvant chemoradiotherapy			Intervention code:		
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:	三甲医院			
	Institution hospital:	Chinese PLA General Hospital	Level of the institution:	Tertiary A hospital			
测量指标: Outcomes:	指标中文名:	PFS			指标类型:	主要指标	
	Outcome:	PFS			Type:	Primary indicator	
	测量时间点:				测量方法:		
	Measure time point of outcome:				Measure method:		
	指标中文名:	OS			指标类型:	主要指标	
	Outcome:	OS			Type:	Primary indicator	
	测量时间点:				测量方法:		
	Measure time point of outcome:				Measure method:		
	指标中文名:	副反应			指标类型:	主要指标	
	Outcome:	side effects			Type:	Primary indicator	
	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:							
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):	无						
Randomization Procedure (please state who generates the random number sequence and by what method):	no						

盲法：	
Blinding：	
原始数据公开时间： The time of sharing IPD：	试验完成后6个月内公开/Within six months after the trial complete
共享原始数据的方式（说明：请填写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络址）：	通过ResMan提供原始数据查询
The way of sharing IPD“(include metadata and protocol, If use web-based public database, please provide the url)：	IPD will be public accessible via 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：	中国人民解放军总医院
Data collection and Management (A standard data collection and management system include a CRF and an electronic data capture：	Chinese PLA General Hospital
数据管理委员会： Data Managemen Committee：	暂未确定/Not yet

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提示：推荐使用IE8.0以上版本 宽屏显示分辨率下使用系统。



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