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## 修改项目信息edit project

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.  
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注册号: Registration number:	ChiCTR1800014739
最近更新日期: Date of Last Refreshed on:	2018/12/19 11:40:30
注册号状态:	预注册
Registration Status:	1008001 Prospective registration
注册题目:	一项前瞻性、开放、随机对照临床研究评估累及野放疗联合化疗对比单纯累及野放疗应用于老年食管鳞癌患者的安全性及有效性
Public title:	Involved-Field Irradiation Radiotherapy Combined with Chemotherapy vs Radiotherapy Alone for Elderly Patients With Esophageal Squamous Cell Carcinoma: A prospective, Open, Randomized Controlled of Clinical Outcomes and Toxicities
研究课题的正式科学名称:	一项前瞻性、开放、随机对照临床研究评估累及野放疗联合化疗对比单纯累及野放疗应用于老年食管鳞癌患者的安全性及有效性
Scientific title:	Involved-Field Irradiation Radiotherapy Combined with Chemotherapy vs Radiotherapy Alone for Elderly Patients With Esophageal Squamous Cell Carcinoma: A prospective, Open, Randomized Controlled of Clinical Outcomes and Toxicities
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:	闫茂慧 Yan Maohui	研究负责人: Study leader:	闫茂慧 Yan Maohui
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 18301071600
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:	yanmaohui1984@sina.com	研究负责人电子邮件: Study leader's E-mail:	yanmaohui1984@sina.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: Applicant address:	北京市海淀区复兴路28号 中国人民解放军总医院 28 Fuxing Road, Haidian District, Beijing, China	研究负责人通讯地址: Study leader's address:	北京市海淀区复兴路28号 中国人民解放军总医院 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: Applicant's institution:	中国人民解放军总医院 General Hospital of PLA medical		

是否获伦理委员会批准: Approved by ethic committee:	是 Yes		
伦理委员会批件文号: Approved No. of ethic committee:	S2018-031-01	伦理委员会批件附件: Approved file of Ethical Committee:	<a href="#">查看附件View</a>
批准本研究的伦理委员会名称: Name of the ethic committee:	中国人民解放军总医院医学伦理委员会 IRB of Chinese PLA General Hospital		
伦理委员会批准日期: Date of approved by ethic committee:	2013/08/26		
伦理委员会联系人: Contact Name of the ethic committee:	曹江 Cao Jiang		
伦理委员会联系地址: Contact Address of the ethic committee:	北京市海淀区复兴路28号 28 Fuxing Road, Haidian District, Beijing, China		
伦理委员会联系人电话: Contact phone of the ethic committee:	+86 010-66937166	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: Primary sponsor:	中国人民解放军总医院 Chinese PLA General Hospital
研究实施负责（组长）单位地址: Primary sponsor's address:	中国北京市海淀区复兴路28号 28 Fuxing Road, Haidian District, Beijing, China
国家: 省(直辖市): 市(区县):	中国 北京市

试验主办单位(项目批准或申办者): Secondary sponsor:	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:	General Hospital of PLA medical	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:	干预性研究				
Study type:	Interventional study				
研究所处阶段:	治疗新技术临床试验				
Study phase:	New Treatment Measure Clinical Study				
研究目的:	评估累及野放疗联合化疗对比单纯累及野放疗应用于老年食管鳞癌患者的安全性及有效性				
Objectives of Study:	To evaluate the efficacy and safety of involved-field irradiation radiotherapy combined with chemotherapy vs radiotherapy alone for elderly patients with esophageal squamous cell carcinoma				
研究设计:	随机平行对照				
Study design:	Parallel				
纳入标准:	①年龄 ≥70 岁； ②临床分期cT2-3N0-2M0所有入组患者； ③病理证实为食管鳞癌； ④均为初次治疗，无法或拒绝进行手术切除； ⑤ECOG评分≤2 分，无放疗禁忌症 ⑥理解放疗、化疗知情同意书内容能力； ⑦没有伴随的其他恶性肿瘤病史； ⑧具有完整的病例资料				
Inclusion criteria	1. Aged ≥70 years; 2. Clinical stages (cT2-3N0-2M0); 3. Pathological examination of esophageal squamous cell carcinoma; 4. For the first treatment, the operation could not be performed or refused to be excised; 5. ECOG scores≤2No contraindication of chemoradiotherapy; 6. Ability to understand the content of informed consent in radiotherapy and chemotherapy; 7. No accompanying history of other malignant tumors; 8. Complete case data.				
排除标准:	①年龄小于70岁 ②病理证实为非鳞癌 ③检查、检验结果提示有食管穿孔、消化道出血风险 ④早期I期食管 ⑤出现远处转移 ⑥曾接受手术、放疗、化疗， 或伴随其他恶性肿瘤 ⑦有放疗禁忌症 ⑧放疗方式为行常规、三维适形放疗 ⑨化疗需大于4周期 ⑩病例资料不完整				
Exclusion criteria:	1. Non squamous cell carcinoma confirmed by pathology; 2. The results of examination and examination suggest the risk of perforation of the esophagus and the bleeding of the digestive tract; 3. Early I stage esophagus; 4. Distant metastasis; 5. Had received surgery, radiotherapy, chemotherapy, or associated with the history of other malignant tumors; 6. Contraindication with radiotherapy and chemotherapy; 7. Radiotherapy for conventional and three-dimensional conformal radiotherapy; 8. Chemotherapy needs more than 4 cycles.				
研究实施时间: Study execute time:	从From2018/02/22至To 2019/12/01				

干预措施: Interventions:	组别:	A	样本量:	15
	Group:	A	Sample size:	
	干预措施:	放疗联合静脉化疗		干预措施代码:
	Intervention:	A	Intervention code:	
	组别:	B	样本量:	15
	Group:	B	Sample size:	
	干预措施:	放疗联合口服化疗		干预措施代码:
	Intervention:	B	Intervention code:	
	组别:	C	样本量:	15
	Group:	C	Sample size:	
	干预措施:	单纯放疗		干预措施代码:
	Intervention:	C	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
	Outcome:	PFS
	测量时间点:	测量方法:
	Measure time point of outcome:	Measure method:
	指标中文名:	OS
	Outcome:	OS
	测量时间点:	测量方法:
	Measure time point of outcome:	Measure method:
	指标中文名:	副反应
	Outcome:	side effects
	测量时间点:	测量方法:
	Measure time point of outcome:	Measure method:
	指标中文名:	缓解率
	Outcome:	
	测量时间点:	
	Measure time point of outcome:	

	Outcome: pCR	
	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: Sample Name:	无NO	组织: Tissue:
	人体标本去向 Fate of sample:	使用后销毁 Destruction after use	说明 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 70 岁 years
			最大 Max age 90 岁 years

性别: 男女均可	Gender: Both
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随机方法 (请说明由何人用什么方法产生随机序列): Randomization Procedure (please state who generates the random number sequence and by what method):	spss软件电脑随机分组SPSS software computer random grouping
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盲法: 未说明
Blinding: Not stated

是否公开试验完成后的统计结果: Calculated Results ater the Study Completed public access:	<div>公开/Public</div> 变更change
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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: <div>选取文件 未选择文件</div> *
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UTN(全球唯一识别码):
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是否共享原始数据: IPD sharing	是Yes
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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): The way of sharing IPD”(include metadata and protocol, If use web-based public database, please provide the url):	通过ResMan提供原始数据查询IPD will be public accessible via ResMan
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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。: Data collection and Management (A standard data collection and management system include a CRF and an electronic data capture :	中国人民解放军总医院Chinese PLA General Hospital
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数据与安全监察委员会: Data and Safety Monitoring Committee:	有/Yes暂未确定/Not yet
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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):	
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Publication information of the protocol/research results report (name of the journal, volume, issue, pages, time; or website):		修改/update
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注册人: Name of Registration:	2018/01/31
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项目来源: Project Origin:	本站
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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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