

审核状态:

该项目已经通过审核,不能再修改项目信息。

Project audit state:

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

返回 Back

注册号:

Registration number:

ChiCTR1800017630

最近更新日期:

Date of Last Refreshed on:

2018/8/7 19:16:28

注册号状态:

预注册

Registration Status:

1008001 Prospective registration

注册题目:

丙泊酚复合地佐辛对胃镜肠镜联合病人的作用

Public title:

Effect of propofol combined with dezocine on patients undergoing indolent both gastroscopy and colonoscopy

研究课题的正式科学名称:

丙泊酚复合地佐辛对胃镜肠镜联合病人的作用

Scientific title:

Effect of propofol combined with dezocine on patients undergoing indolent both gastroscopy and colonoscopy

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:

张立敏

研究负责人: 张立敏

Applicant:

Zhang Limin

Study leader:

Zhang Limin

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+86 13115501086

研究负责人电话:

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研究负责人电子邮件:

Study leader's

E-mail:

chizhang75@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: 中国黑龙江哈尔滨颐园
街 37 号哈尔滨医科大学
附属第四医院麻醉科

研究负责人通
讯地址: 中国黑龙江哈尔滨颐园
街 37 号哈尔滨医科大
学附属四院

Applicant address: 37 Yiyuan Street, Harbin,
Heilongjiang, China

Study leader's address: 37 Yiyuan Street, Harbin,
Heilongjiang, 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: 哈尔滨医科大学附属第四医院

Applicant's Department of Anaesthesiology, The Fourth Affiliated Hospital of Harbin Medical
institution: University

是否获伦理委员会批
准: 否

Approved by ethic committee: NO

伦理委员会批件文号:
Approved No. of ethic
committee:

伦理委员会批件附件:
Approved file of Ethical
Committee:

批准本研究的伦理委
员会名称:

Name of the ethic committee:

伦理委员会批准日期:

Date of approved by ethic 2013/08/26
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 哈尔滨医科大学附属第四医院麻醉科
长)
单
位:

Primar
y
spons
or:
Department of Anaesthesiology, The Fourth Affiliated Hospital of Harbin Medical University

研究
实施
负责
(组 中国黑龙江哈尔滨颐园街 37 号
长)
单
位
地
址:

Primar
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spons
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addres
s:
37 Yiyuan Street, Harbin, Heilongjiang, China

试验
主办
单位
(项
目批
准或
申办
者):
Seco
ndary
spons
or:
国家: 中国
省(直辖
市): 黑龙江
市(直
辖市):
Country: China
Province: Heilongjiang
City:
单位(医
院): 哈尔滨医科大学附属第
四医院麻醉科
具体地
址: 哈尔滨颐园街 37 号哈尔滨医科大学附属第四
Institution
hospital: Department of Anaesthesiology,
The Fourth Affiliated Hospital of
Harbin Medical University
Address: 37 Yiyuan Street, Harbin, Heilongjiang, China

经费
或物
资来
源：
自筹经费

Source
(s) of
fundin self-help fundraising
g:

研究
疾 无痛胃镜肠镜联合检查和/或治疗
病：

Target
diseas patients undergoing indolent both gastroscopy and colonoscopy
e:

研究
疾病
代
码：

Target
diseas
e
code:

研究
类 干预性研究
型：

Study
type: Interventional study

研究
所处
阶 治疗新技术临床试验
段：

Study
phase New Treatment Measure Clinical Study
:

研究
目
的：
虽然胃肠镜镇痛镇静的最好方法仍在讨论中，但是发现一种充足的胃肠镜镇痛镇静方法是很重要的。镇静状态下的咽喉刺激能引起反射反应。丙泊酚复合阿片类镇痛药被推荐为胃肠镜镇静方法，但是，相关的咳嗽反射抑制作用、呼吸抑制、体动反应仍然不清楚。本次试验将评价丙泊酚分别复

合地佐辛、舒芬太尼、芬太尼对胃肠镜的作用。我们假设较好的作用可能在丙泊酚复合地佐辛组中得到。我们将记录丙泊酚复合以下阿片类药物或单纯丙泊酚镇静下的咳嗽反射的发生率和程度、呼吸抑制、体动反应的发生率。

The best methods for inducing analgesia and sedation for gastroscopy and colonoscopy are still debated but finding an adequate regimen of analgesia and sedation is important. Stimulation of the larynx under sedation can cause reflex responses. Propofol with opioids has been recommended for sedation of Object gastroscopy and colonoscopy but the effects on cough reflex suppression, respiratory depression, body ives of movement remain unclear. This trial will evaluate the effects of propofol combined with small doses of Study: dezocine, sufentanil or fentanyl for gastroscopy and colonoscopy. We hypothesise that better performance may be obtained with a combination of propofol and dezocine. We will observe the incidence and degree of reflex coughing and gagging, respiratory depression, body movement under sedation when using propofol combined with one of the above drugs or propofol alone.

研究
设计 随机平行对照
计:

Study
design Parallel
:

纳入
标准 ASA I-II 级年龄 18 至 85 岁计划联合胃肠镜检或治疗的病人入选。
准:

Inclusi
on ASA I-II level patients aged 18-85 years and scheduled for gastroscopy and colonoscopy will be
criteri included.
a

排除
标准 年龄大于 85 岁或小于 18 岁、BMI>30kg/m²、术前存在循环、呼吸及神经系统等系统性疾病、术前血红蛋白低于 70g/L、白蛋白低于 30g/L 者。
准:

Exclusi
on BMI>30 kg/m²; pre-existent circulation, respiratory and nervous systemic diseases; hemoglobin <70g/L;
criteri albumin< 30 g/L.
a:

研究
实施
时间 从 From2018/08/01 至 To 2019/12/31
间:
Study
execut

e
time:

干预措施: Interventions:	组别:	芬太尼组	样本量:	100
	Group:	fentanyl group	Sample size:	
	干预措施:	芬太尼+丙泊酚	干预措施代码:	
	Intervention:	芬太尼组	Intervention code:	
	组别:	舒芬太尼组	样本量:	100
	Group:	sufentanil group	Sample size:	
	干预措施:	舒芬太尼+丙泊酚	干预措施代码:	
	Intervention:	舒芬太尼组	Intervention code:	
	组别:	地佐辛组	样本量:	100
	Group:	dezocine group	Sample size:	
	干预措施:	地佐辛+丙泊酚	干预措施代码:	
	Intervention:	地佐辛组	Intervention code:	
组别:	对照组	样本量:	100	
Group:	control group	Sample size:		
干预措施:	丙泊酚+生理盐水	干预措施代码:		
Intervention:	对照组	Intervention code:		

研究实施地点: Countries of recruitment and research settings:	国家:	中国	省(直辖市):	黑龙江	市(区县):	
Country:	China	Province:	Heilongjiang	City:		
单位(医院):	哈尔滨医科大学附属第四医院	单位级别:	三级甲等医院			
Institution of hospital:	The fourth affiliated hospital of Harbin medical university	Level of the institution:	Tertiary A hospital			

测量指标: Outcome:	指标中文名:	脉搏氧饱和度
Outcome:		oxygen saturation

es:

测量时间点:

测量方法:

Measure time point of outcome:

Measure method:

指标中文名:

血压

Outcome:

blood pressure

测量时间点:

测量方法:

Measure time point of outcome:

Measure method:

指标中文名:

诱导时间

Outcome:

induction time

测量时间点:

测量方法:

Measure time point of outcome:

Measure method:

指标中文名:

丙泊酚的诱导剂量

Outcome:

the induction dosage of propofol

测量时间点:

测量方法:

Measure time point of outcome:

Measure method:

指标中文名:

反射性咳嗽和呕吐的发生率和程度

Outcome:

the incidence and degree of reflex coughing and gagging

测量时间点:

测量方法:

Measure time point of outcome:

Measure method:

指标中文名:

体动发生率

Outcome:

incidence of body movement

测量时间点:

测量方法:

Measure time point of outcome:

Measure method:

指标中文名:

呼吸抑制发生率

Outcome:

incidence of respiratory depression

测量时间点:

测量方法:

Measure time point of outcome:

Measure method:

指标中文名:

托下颌的使用率

Outcome:

the use of jaw thrust

测量时间点:		测量方法:
Measure time point of outcome:		Measure method:
指标中文名:	辅助呼吸的使用率	
Outcome:	incidence of assisted ventilation	
测量时间点:		测量方法:
Measure time point of outcome:		Measure method:
指标中文名:	血管收缩药的使用率	
Outcome:	incidence of using vasoactive drugs	
测量时间点:		测量方法:
Measure time point of outcome:		Measure method:
指标中文名:	胃肠镜持续时间	
Outcome:	duration of procedure	
测量时间点:		测量方法:
Measure time point of outcome:		Measure method:
指标中文名:	Steward 评分	
Outcome:	Steward score	
测量时间点:		测量方法:
Measure time point of outcome:		Measure method:
指标中文名:	丙泊酚的总用量	
Outcome:	the total dosage of propofol	
测量时间点:		测量方法:
Measure time point of outcome:		Measure method:
指标中文名:	苏醒时间	
Outcome:	awake time	
测量时间点:		测量方法:
Measure time point of outcome:		Measure method:
指标中文名:	疼痛评分	
Outcome:	the patient's pain score	

测量时间点: 测量方法:

Measure time point of outcome: Measure method:

指标中文名: 术后恶心发生率

Outcome: incidence of postoperative vomiting

测量时间点: 测量方法:

Measure time point of outcome: Measure method:

指标中文名: 术后头晕发生率

Outcome: incidence of postoperative dizziness

测量时间点: 测量方法:

Measure time point of outcome: Measure method:

指标中文名: 术后头痛发生率

Outcome: incidence of postoperative headache

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: 正在进行
Recruiting status: Recruiting

年龄范围:
Participant age:

最小 Min 18 岁 years
age

最大 Max 85 岁 years
age

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): 由研究组专人采用随机数字表法将入组患者随机分为四组

Randomization

Procedure (please state who generates the random number According to random number table method by a member of our team ,the recruited subjects were divided into 4 groups

sequence and by what
method):

盲法: **Not stated**

Blinding
: Not stated

是否
公开
试验
完成
后的
统计
结果:

Calculat
ed
Results
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Study
Comple
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public
access:

变更 change

上传
的试
验完
成后
的统
计结
果:

Statistic
al [点击下载 download](#) 重传 Upload: *

results
after
complet
ion of
the test
file
upload:

UTN(
全球
唯一
识别

码):

原始数据公开时间: 即时公开/Real time access
The time of sharing IPD:

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): **Not stated**

The way of sharing IPD"(include
metadata and protocol, If use
web-based public database, please
provide the url): **Not stated**

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。: **Not stated**

Data collection and Management (A
standard data collection and
management system include a CRF and
an electronic data capture : **Not stated**

数据管理委员会: 暂未确定/Not yet
Data Managemen Committee:

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: 2018/08/07
Name of Registration:

项目来源: 本站
Project Origin: