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审核状态: 该项目通过审核
Project audit state: This trial is Successful.

* 填写语言: Language:	中文和英文/Chinese And English
* 注册号状态: Registration Status:	预注册/Prospective registration
* 注册题目:	艾司氯胺酮对老年无痛胃肠镜检查的研究
* Public title:	Eesketamine for painless gastroenteroscopy in the elderly
注册题目简写:	
English Acronym:	
* 研究课题的正式科学名称:	艾司氯胺酮对老年无痛胃肠镜检查的研究
* Scientific title:	Eesketamine for painless gastroenteroscopy in the elderly
研究课题的正式科学名称简写:	
Scientific title acronym:	
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:	万向前	* 研究负责人:	万向前
* Applicant:	Xiangqian Wan	* Study leader:	Xiangqian Wan
* 申请注册联系人电话: Applicant's telephone:	+86 183 8101 5045 请输入国际区号如:+86 xxx,区号与号码之间添加一个空格 此属于公开数据项，建议填写工作电话 Please enter the phone area code such as +86 xxx and add a space between the area code and the number This is public data. Please provide a work phone number.	* 研究负责人电话: Study leader's telephone:	+86 183 8101 5045 请输入国际区号如:+86 xxx,区号与号码之间添加一个空格 此属于公开数据项，建议填写工作电话 Please enter the phone area code such as +86 xxx and add a space between the area code and the number This is public data. Please provide a work phone number.
申请注册联系人传真:		研究负责人传真:	
* 申请注册联系人电子邮件: Applicant's E-mail:	286624122@qq.com	* 研究负责人电子邮件: Study leader's E-mail:	286624122@qq.com

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* 申请注册联系人通讯地址:	成都市龙泉驿区鲸龙路121号	* 研究负责人通讯地址:	成都市龙泉驿区鲸龙路121号
* Applicant's address:	No.121,JinglongRoad,longquanyiDistrict,Chengdu	* Study leader's address:	No.121,JinglongRoad,longquanyiDistrict,Chengdu
申请注册联系人邮政编码: Applicant's postcode:	610100	研究负责人邮政编码: Study leader's postcode:	610100
* 申请人所在单位:	四川护理职业学院附属医院(四川省第三人民医院)	* 研究负责人所在单位:	四川护理职业学院附属医院(四川省第三人民医院)
* Affiliation of the Registrant:	The Affiliated Hospital of Sichuan Nursing Vocational College (the Third People's Hospital	* Affiliation of the Leader:	The Affiliated Hospital of Sichuan Nursing Vocational College (the Third People's Hospital
* 是否获伦理委员会批准: Approved by ethic committee:	○ 是/Yes ○ 否/No		
* 伦理委员会批件文号: Approved No. of ethic committee:	KY-2025-0104	* 伦理委员会批件附件: Approved file of Ethical Committee:	已上传附件/Attachment 请将与研究相关的所有伦理批件完整页合并上传（初审、复审、修正案、跟踪审查批件）
* 批准本研究的伦理委员会名称:	四川护理职业学院附属医院(四川省第三人民医院)医学验伦理委员会		
* Name of the ethic committee:	Medical Ethics Committee of the Affiliated Hospital of Sichuan Nursing Vocational College (the Third People's Hos		
* 伦理委员会批准日期: Date of approved by ethic committee:	2025-02-25		
* 伦理委员会联系人:	谭玲		
* Contact Name of the ethic committee:	Ling Tan		
* 伦理委员会联系地址:	成都市龙泉驿区鲸龙路121号		
* Contact Address of the ethic committee:	No.121,JinglongRoad,longquanyiDistrict,Chengdu		
* 伦理委员会联系人电话: Contact phone of the ethic committee:	+86 28 8843 8361 请输入国际区号如:+86 xxx,区号与号码之间添加一个空格 Please enter the phone area code such as +86 xxx and add a space between the area code and the number	伦理委员会联系人邮箱: Contact email of the ethic committee:	
国家批准文号: Approved No.:	(选填Optional)	国家批准附件: Approved file:	未上传附件No upload
国家批准日期: Date of approved:			

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* 研究计划书:
Study plan file:

已上传附件/Attachment（仅用于审核，不公开 for prejudication of registration only, will not be published）

上传与伦理审查对应版本的最新研究计划书

* 知情同意书:
I informed consent file:

已上传附件/Attachment（仅用于审核，不公开 for prejudication of registration only, will not be published）

上传与伦理审查对应版本的最新知情同意书，如免除知情同意，请上传对应的免除知情同意申请

* 研究实施负责(组长)单位: 四川护理职业学院附属医院(四川省第三人民医院)

* Primary sponsor: The Affiliated Hospital of Sichuan Nursing Vocational College (the Third People's Hospital of Sichuan Province)

* 研究实施负责(组长)单位地址: 成都市龙泉驿区鲸龙路121号

* Primary sponsor's address: No.121,JinglongRoad,longquanyiDistrict,Chengdu

* 试验主办单位(即项目批准或申办者):
Secondary sponsor:

* 国家:	中国	* 省(直辖市):	四川省	市(区县)	成都市
* Country:	China	* Province:	Sichuan Province	City	Chengdu city
* 单位:	四川护理职业学院附属医院(四	* 具体地址:	成都市龙泉驿区鲸龙路121号		
	每格只填写一个单位(医院)				
* Institution:	The Affiliated Hospital of Sichu	* Address:	No.121,JinglongRoad,longquanyiDistrict,Chengdu		
	Input only one institution				

* 经费或物资来源: 2024年度临床科学研究基金

* Source(s) of funding: 2024 Clinical Research Science Fund

* 研究疾病: 无

研究疾病代码:

* Target disease: None

Target disease code:

* 研究类型:
Study type: 干预性研究/Interventional study

* 研究设计:
Study design: 随机平行对照/Parallel

* 研究所处阶段:
Study phase: 上市后药物/4

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* 研究目的:	
* Objectives of Study:	Discussing the effect of small doses of esketamine combined with propofol on painless gastroenteroscopy in the elderly outpatient clinic
药物成份或治疗方案详述:	
Description for medicine or protocol of treatment in detail:	
* 纳入标准:	1、年龄为60-80周岁的健康患者；2、美国麻醉医师协会分级（ASA分级）为Ⅰ~Ш级；3、体重指数（BMI）在18-30kg/m^2；4、愿意配合并签署同意书的患者。
* Inclusion criteria:	1 .Healthy patients aged 60-80 years old 2. American Society of Anesthesiologists classification (ASA) grades I to Ш 3. Body mass index (BMI) at 18-30 kg/m^2
* 排除标准:	1、严重的心血管或肺部疾病(高血压未受控制[收缩压>=180 mmHg]、冠心病、心肌梗死、充血性心力 衰竭、左室射血分数<40%、快速性心律失常、二级或以上房室传导阻滞、病窦综合征、严重心动过缓[心率< 50次/分]、肺疾病、慢性阻塞性肺疾病、哮喘、肺气肿、支气管扩张或肺纤维化）；2、肾或肝功能障碍（Child Pugh C级或需要肾脏替代治疗）；3、神经认知障碍（帕金森病或阿尔茨海默病）或精神疾病疾病；4、癫痫发作或癫痫；5、血糖控制差的糖尿病患者（空腹血糖>=11.1mmol/L） 6、对药物研究过敏；7、酒精中毒或术前
* Exclusion criteria:	

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fraction <40%, tachyarrhythmia, secondary or above atrioventricular block, sick sinus syndrome, severe bradycardia [heart rate <50 beats / min], lung disease, chronic obstructive pulmonary disease, asthma,emphysema, bronchiectasis or pulmonary fibrosis)

* 研究实施时间: Study execute time: 2025-01-01 - 2026-12-31

* 征募观察对象时间: Recruiting time: 2025-05-01 - 2025-12-31

注意：如尚无受试者入组，填未来时间；如已入组，填首例知情同意签署日期。回顾性研究填收集这部分病例资料或组织样本开展研究的时间

* 干预措施: Interventions:

* 组别:	艾司氯胺酮组（S 组）
* Group:	Esketamine group (Group S)
* 干预措施:	术前由麻醉门诊医生评估患者情况，根据纳入与排除标准，选择适应病例告知并签署麻醉同意书。患者入室后先平卧位，监测并记录生命体征（无创血压、心电图、外周氧饱
	每格只填写一个干预措施
* Intervention:	The anesthesia clinic doctor evaluated the patient before the surgery, and the anesthesia consent was signed according to the inclusion and exclusion criteria. After
	Please input only one Measure
* 样本量:	158
* Sample size:	
干预措施代码:	
Intervention code:	每格只填写一个代码/Please input only one code

* 组别:	对照组（C 组）
* Group:	Control group(Group C)
* 干预措施:	术前由麻醉门诊医生评估患者情况，根据纳入与排除标准，选择适应病例告知并签署麻醉同意书。患者入室后先平卧位，监测并记录生命体征（无创血压、心电图、外周氧饱
	每格只填写一个干预措施
* Intervention:	The anesthesia clinic doctor evaluated the patient before the surgery, and the anesthesia consent was signed according to the inclusion and exclusion criteria. After
	Please input only one Measure
* 样本量:	158
* Sample size:	
干预措施代码:	
Intervention code:	每格只填写一个代码/Please input only one code

* 样本总量: Total sample size: 316

* 研究实施地点: Countries of recruitment and research settings: 多中心研究完整填写所有分中心

* 国家:	中国	* 省(直辖市):	四川省	市(区县):	成都市
* Country:	China	* Province:	Sichuan Province	City:	Chengdu City
* 单位(医院):	四川护理职业学院附属医院(四川省第三人民医院)			* 单位级别:	三级
每格只填写一个单位(医院)				例如：三级，三甲，二级，二乙，一级，社区卫生服务中心，大学，如无可填写"无 N/A"，非行政级别	

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Secondary B, Primary, Community Health Service Center, University, or N/A, no administrative level.

每项指标分框填写，如有区分指标类型，请准确选择

* 测量指标: Outcomes:

* 指标中文名:	低氧血症的发生率
	每格只填写一个指标
* Outcome Name:	Incidence of hypoxemia and hypotension
	Input only one outcomes name
测量时间点:	给药后（T1）
Measure time point of outcome:	After drug administration (T1)
* 指标类型:	主要指标/Primary indicatc
* Type:	
测量方法:	监护仪直接测量
Measure method:	Measured directly by the monitor

* 指标中文名:	低血压的发生率
	每格只填写一个指标
* Outcome Name:	The incidence of hypotension
	Input only one outcomes name
测量时间点:	给药后（T1）
Measure time point of outcome:	After drug administration (T1)
* 指标类型:	主要指标/Primary indicatc
* Type:	
测量方法:	监护仪直接测量
Measure method:	Measured directly by the monitor

填写标本名称即可，如不涉及可填'无'

* 采集人体标本: Collecting sample(s) from participants:

* 标本中文名:	无
	每格只填写一个，如"血液"、"唾液"等
* Sample Name:	None
	Input only one,such as "Blood","Saliva" etc.
* 人体标本去向:	其它/Others
* Fate of sample:	
组织:	None
	请说明取自何组织或器官
Tissue:	None
	Specify take from which tissue or organ
说明:	
	说明保存年限或其他去向等
Note:	
	Specify expected time of preservation or other fate

征募研究对象情况: Recruiting status: 尚未开始/Not yet recruiting

* 年龄范围: Participant age: 最小/Min age 60 岁/years

性别:

* 年龄范围:

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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):	负责人指导一名不参与本临床试验的麻醉护士使用SPSS25.0版产生随机数字
* Randomization Procedure (please state who generates the random number sequence and by what method):	The director instructed an anesthesia nurse who did not participate in this clinical trial to generate random numbers using version SPSS25.0.
研究对象是否签署知情同意书: Sign the informed consent:	○ 是/Yes ○ 否/No
随访时间: Length of follow-up(include time point of outcome measure):	1 天/Day(s)
* 隐蔽分组方法和过程:	一名不参与本临床试验的麻醉护士采用spss25.0产生随机数字，共316个随机数字，将拟纳入的患者分为试验组（S 组）和对照组（C 组），并用密封信封封闭好，并根据产生的数字配好相应的药物交给麻醉医师，参与麻醉管理的麻醉医师不清楚分组和药物情况，记录相应的临床情况，参与术后随访的另外一人不清楚患者分组和数字用药情况，密切随访并填写CRF表。
* Process of allocation concealment	An anesthesia nurse who does not participate in this clinical trial using spss25.0 to produce random numbers, a total of 316 random numbers, the patients to be included into trial group (S group) and control group (group C), and sealed envelope, and the corresponding drug according to the number to anesthesiologist, the anesthesiologist involved in anesthesia management is not clear grouping and drug, record the corresponding clinical situation, the postoperative follow-up another unclear patient group and digital drug,
* 盲法:	双盲; 麻醉主治医师不知晓分组以及药物配方。另外一名麻醉医师随访患者，该名麻醉医师也不知晓分组以及用药情况。患者本人也不知晓分组情况。
* Blinding:	Double-blind; blinded of group and drug formulation. Another anesthesiologist followed the patient, who was not aware of the group or medication. The patient himself was not aware of the group status.
揭盲或破盲原则和方法:	揭盲在试验结束后，统计分析前进行，生成分配序列的人和研究主要负责人同时在场时揭盲，揭盲前需检查信封是否保存完好。记录揭盲时间、是否符合规程和密封信封验收情况。当受试者出现了严重不良反应，若不知道受试者所用药物受试者就不能得到正确处理的情况下，随访负责人需与研究负责人讨论后，才可破盲，破盲需有见证人在场。经讨论同意破盲后，保管应急信封的课题负责人将相应信封交给随访负责人。打开应急信件时要在信封上写上打开应急信件的日期、签名和理由。随访负责人随后需填写一份“受试者破盲报道”。

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Rules of unsolved or leading blinding:	Record the time, compliance with procedures and acceptance of sealed envelope. When the subject has a serious adverse reaction, if the subject is not properly treated without the treatment of the subject, then the head of the subject can be present. After agreeing to break the blindness, the project leader who kept the
统计方法名称:	数据分析使用IBM SPSS软件25.0版本（SPSS Inc.，Chicago, IL, USA）。连续变量以平均值± SD或中位数（IQR）表示，分类变量以数字（百分比）表示。连续变量的正态性假设采用Shapiro-Wilk检验进行评估。对连续正态分布变量和非正态分布变量，分别采用独立样本t检验或Mann-Whitney U检验来评估组间差异。各组间分类变量的比较采用卡方检验。P值<为0.05被认为有统计学意义。
Statistical method:	Data were analyzed using IBM SPSS software version 25.0 (SPSS Inc., Chicago, IL, USA). Continuous variables are presented as mean ± SD or median (IQR), and categorical variables are presented as numbers (percentage). The assumption of normality for continuous variables was assessed using the Shapiro-Wilk test. Independent sample t-test or Mann-Whitney U test were used for continuous and non-normally distributed variables,respectively. Comparison of categorical variables between the groups was performed
试验完成后的统计结果:	
Calculated Results ater the Study Completed:	
上传试验完成后的统计结果: Statistical results after completion of the test file upload:	未上传附件No upload
是否公开试验完成后的统计结果: Calculated Results after the Study Completed public access:	公开/Public
全球唯一识别码: UTN:	
* 是否共享原始数据: IPD sharing:	○ 是/Yes ○ 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):	原始数据在试验完成后6个月内公开，采用临床试验公共平台管理和公布
* The way of sharing IPD"(include metadata and protocol, If use web-based public database, please provide the url):	Original data will be shared 6 month after the trial complete on the clinical trial public platform

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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:	After the study, Printing CRFs will be locked in reference room of anesthesiology department and managed by researchers. Electronic data will be saved in the data bank of anesthesiology department and only can be contacted by special researcher.
数据与安全监察委员会: Data and Safety Monitoring Committee:	有/Yes
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):	
注册人: Name of Registration:	万向前[365685]
注册时间: Date of Registration:	2025-03-26 00:00:00
项目来源: Date of Registration:	注册中心

提交submit　< 返回列表

提示：当您确认您的信息已经完整无误后，您可以点击“提交”按钮提请工作人员对该信息进行审核，否则您可以点击“保存”按钮保存信息但是暂不提请审核。

Tip: after you have completed the filling all the information in the registration form, you can select "Submit" button to apply for verification. Otherwise, select "Save" to save it and you can continue to work on filling.