ChiCTR2000029308 版本V1.8 版本创建时间2020/3/8 16:10:31 中国临床试验注册中心

审核状态: Project audit state:	**通过审核** Successful
注册号: Registration number:	ChiCTR2000029308
最近更新时间: Date of Last Refreshed on:	2020/2/12 10:42:45
注册号状态:	预注册
Registration Status:	Prospective registration
填写语言:	中文和英文
Language:	Chinese And English
注册题目:	一项评价洛匹那韦/利托那韦和干扰素-α2b联合治疗武汉新型冠状病毒肺炎(COVID-19)住院患者的疗效和安全性随机、开放、空白对照的研究
Public title:	A randomized, open-label, blank-controlled trial for the efficacy and safety of lopinavir-ritonavir and interferon-alpha 2b in hospitalization patients with novel coronavirus pneumonia (COVID-19)
注册题目简写:	
Public title acronym:	
研究课题的正式科学名称:	一项评价洛匹那韦/利托那韦和干扰素-α2b联合治疗武汉新型冠状病毒肺炎(COVID-19)住院患者的疗效和安全性随机、开放、空白对照的研究
Scientific title:	A randomized, open-label, blank-controlled trial for the efficacy and safety of lopinavir-ritonavir and interferon-alpha 2b in hospitalization patients with novel coronavirus pneumonia (COVID-19)
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:	
在其它机构的注册号: Secondary ID:	

申请注册联系人:	刘颖	研究负责人:	黄朝林
Applicant:	Liu Ying	Study leader:	Huang Chaolin
申请注册联系人电话: Applicant telephone:	+86 027 85509088	研究负责人电话: Study leader's telephone:	+86 15307173189
申请注册联系人传真 : Applicant Fax:	+86 027 85509002	研究负责人传真: Study leader's fax:	+86 027 85509002
申请注册联系人电子邮件: Applicant E-mail:	whsjytyy_gcp@163.com	研究负责人电子邮件: Study leader's E-mail:	88071718@qq.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:	湖北省武汉市东西湖区银潭路1号	研究负责人通讯地址:	湖北省武汉市东西湖区银潭路1号
Applicant address:	1 Yintan Road, Dongxihu District, Wuhan, Hubei, China	Study leader's address:	1 Yintan Road, Dongxihu District, Wuhan, Hubei, China
申请注册联系人邮政编码: Applicant postcode:	430023	研究负责人邮政编码: Study leader's postcode:	430023
申请人所在单位:	武汉市金银潭医院（武汉市传染病医院）		
Applicant's institution:	Wuhan Jinyintan Hospital (Wuhan Infectious Diseases Hospital)		

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:	KY-2020-02.01	伦理委员会批件附件: Approved file of Ethical Committee:	查看附件View
批准本研究的伦理委员会名称:	武汉市传染病医院医学伦理委员会		
Name of the ethic committee:	Medical Ethics Committee of Wuhan Infectious Disease Hospital		
伦理委员会批准日期: Date of approved by ethic committee:	2020-01-10		
国家FDA批准文号: Approved No. of SFDA:		国家FDA批准附件: Approved file of SFDA:	

国家FDA批准日期: Date of approved by SFDA:	
研究实施负责（组长）单位:	武汉市金银潭医院（武汉市传染病医院）
Primary sponsor:	Wuhan Jinyintan Hospital (Wuhan Infectious Diseases Hospital)
研究实施负责（组长）单位地址:	湖北省武汉市东西湖区银潭路1号
Primary sponsor's address:	1 Yintan Road, Dongxihu District, Wuhan, Hubei, 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):	湖北	市(区县):	武汉
	Country:	China	Province:	Hubei	City:	Wuhan
	单位(医院):	武汉市金银潭医院（武汉市传染病医院）	具体地址:	东西湖区银潭路1号		
	Institution hospital:	Wuhan Jinyintan Hospital (Wuhan Infectious Diseases Hospital)	Address:	1 Yintan Road, Dongxihu District		
	国家:	中国	省(直辖市):	北京	市(区县):	
	Country:	China	Province:	Beijing	City:	
	单位(医院):	中日友好医院	具体地址:	朝阳区樱花园东街		
	Institution hospital:	China-Japan Friendship Hospital	Address:	East Street, Sakura Garden, Chaoyang District		

经费或物资来源:	自筹
Source(s) of funding:	Self-financing
研究疾病:	新型冠状病毒肺炎(COVID-19)
Target disease:	Novel Coronavirus Pneumonia (COVID-19)
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:	评价与标准治疗相比，洛匹那韦/利托那韦和干扰素-α2b联合治疗新型冠状病毒感染的成人住院患者的疗效和安全性。
Objectives of Study:	Evaluate the efficacy and safety of lopinavir-ritonavir and interferon-α2b compared to standard treatment in adult hospitalized patients with novel coronavirus infection.
研究设计:	随机平行对照
Study design:	Parallel
纳入标准:	1.成人（定义为≥ 18 岁）； 2.在尚未开发出快速诊断试剂盒情况下，经过临床诊断的不明原因病毒性肺炎患者；或经过PCR确证的新型冠状病毒感染患者； 3.症状发作与随机入组之间的时间间隔在10天以内，症状发作主要以发热作为判定依据，若无发热可使用咳嗽或其他相关症状； 4.静息未吸氧状态下，患者SPO2≤94%，或氧合指数小于300mmHg。
Inclusion criteria	1. Adult aged >=18years old; 2. Patients with unexplained viral pneumonia that have been clinically diagnosed or patients with novel coronavirus infection confirmed by PCR when no rapid diagnostic kit has been developed; 3. The interval between the onset of symptoms and randomized is within 10 days. The onset of symptoms is mainly based on fever. If there is no fever, cough or other related symptoms can be used; 4. In the state of no oxygen at rest, the patient's SPO2<=94% or the oxygenation index is less than 300mmHg.
排除标准:	1.任何不能让方案安全进行的情况； 2.对洛匹那韦/利托那韦的已知过敏或超敏反应； 3.谷丙转氨酶 (ALT)/谷草转氨酶（AST）升高超过正常上限 5 倍； 4.禁用于洛匹那韦/利托那韦治疗且在研究期间不能更换或停用的药物，例如 CYP3A 抑制剂； 5.妊娠：育龄女性妊娠试验阳性； 6.已知 HIV 感染，因为担心如果未与其他抗 HIV 药物联合使用，会对洛匹那韦/利托那韦产生耐药性； 7.患者可能在 72h 内转至非参与医院； 8.研究者认为不适合者。
Exclusion criteria:	1. Any situation that makes the programme cannot proceed safely; 2. Known allergy or hypersensitivity reaction to lopinavir / ritonavir; 3. Increase in alanine aminotransferase (ALT) / aspartate aminotransferase (AST) is more than 5 times the upper limit of normal; 4. Use of medications that are contraindicated with lopinavir / ritonavir and that cannot be replaced or stopped during the study period, such as CYP3A inhibitors; 5. Pregnancy: positive pregnancy test for women of childbearing age; 6. Known HIV infection, because of concerns about the development of resistance to lopinavir/rionavir if used without combination with other anti-HIV drugs; 7. Patient likely to be transferred to a non-participating hospital within 72 hours; 8. Researchers consider unsuitable.
研究实施时间: Study execute time:	从From2020-01-10至To 2021-01-10

干预措施: Interventions:				
	组别:	干预组	样本量:	80
	Group:	intervention group	Sample size:	

干预措施:	洛匹那韦利托那韦片（每片含洛匹那韦 200 mg，利托那韦 50 mg），一日2次，一次2片	干预措施代码:		
Intervention:	Lopinavir-ritonavir tablets (each containing 200 mg of lopinavir and 50 mg of ritonavir), twice a day, 2 tablets at a time	Intervention code:		
组别:	对照组	样本量:	80	
Group:	Control group	Sample size:		
干预措施:	标准治疗	干预措施代码:		
Intervention:	Conventional standardized treatment	Intervention code:		

研究实施地点: Countries of recruitment and research settings:	国家:	中国	省(直辖市):	湖北	市(区县):	武汉
	Country:	China	Province:	Hubei	City:	Wuhan
	单位(医院):	武汉市金银潭医院（武汉市传染病医院）	单位级别:	三级医院		
	Institution hospital:	Wuhan Jinyintan Hospital（Wuhan Infectious Diseases Hospital)	Level of the institution:	Tertiary Hospital		

测量指标: Outcomes:	指标中文名:	入组28天临床改善时间	指标类型:	主要指标
	Outcome:	Clinical improvement time of 28 days after randomization	Type:	Primary indicator
	测量时间点:		测量方法:	
	Measure time point of outcome:		Measure method:	
	指标中文名:	7分等级量表	指标类型:	主要指标
	Outcome:	The 7-point scale	Type:	Primary indicator
	测量时间点:		测量方法:	
	Measure time point of outcome:		Measure method:	
	指标中文名:	7分：死亡	指标类型:	主要指标
	Outcome:	7 points: death	Type:	Primary indicator
	测量时间点:		测量方法:	
	Measure time point of outcome:		Measure method:	
	指标中文名:	6分：住院接受ECMO和 / 或机械通气	指标类型:	主要指标
	Outcome:	6 points: admission to ECMO and / or mechanical ventilation	Type:	Primary indicator
	测量时间点:		测量方法:	
	Measure time point of outcome:		Measure method:	
	指标中文名:	5分：住院接受无创通气和 / 或高流量氧疗	指标类型:	主要指标
	Outcome:	5 points: Hospitalized for non-invasive ventilation and / or high-flow oxygen therapy	Type:	Primary indicator
	测量时间点:		测量方法:	
	Measure time point of outcome:		Measure method:	
	指标中文名:	4分：住院接受氧疗	指标类型:	主要指标
	Outcome:	4 points: hospitalization for oxygen therapy	Type:	Primary indicator
	测量时间点:		测量方法:	
	Measure time point of outcome:		Measure method:	
	指标中文名:	3分：住院不需要接受氧疗	指标类型:	主要指标
	Outcome:	3 points: Hospitalization does not require oxygen therapy	Type:	Primary indicator
	测量时间点:		测量方法:	

Measure time point of outcome:		Measure method:	
指标中文名:	2分：出院但未恢复正常功能状态	指标类型:	主要指标
Outcome:	2 points: discharged but not restored to normal functional status	Type:	Primary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	
指标中文名:	1分：出院已恢复正常功能状态	指标类型:	主要指标
Outcome:	1 point: discharged to normal function	Type:	Primary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	
指标中文名:	1.关键次要终点为至临床改善的时间（TTCI）	指标类型:	次要指标
Outcome:	The key secondary endpoint was time to clinical improvement (TTCI)	Type:	Secondary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	
指标中文名:	2. 随机后第7、14和28天，7分等级量表各分类的患者比例	指标类型:	次要指标
Outcome:	Proportion of patients in each category of the 7-point scale on days 7, 14, and 28 after randomization;	Type:	Secondary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	
指标中文名:	3. 第28天病死率	指标类型:	次要指标
Outcome:	mortality on day 28	Type:	Secondary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	
指标中文名:	4. 机械通气持续时间（天）	指标类型:	次要指标
Outcome:	Duration of mechanical ventilation(days)	Type:	Secondary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	
指标中文名:	5. 氧疗持续时间（天）	指标类型:	次要指标
Outcome:	Duration of oxygen therapy (days)	Type:	Secondary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	
指标中文名:	6. 住院持续时间（天）	指标类型:	次要指标
Outcome:	Duration of hospitalization (days)	Type:	Secondary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	
指标中文名:	7.呼吸道/血/肛拭子标本中病毒动态变化	指标类型:	次要指标
Outcome:	Dynamic changes of virus in respiratory / blood / anal swab specimens	Type:	Secondary indicator
测量时间点:		测量方法:	

Measure time point of outcome:		Measure method:	
指标中文名:	8.严重药物不良事件频率	指标类型:	次要指标
Outcome:	Frequency of Serious Adverse Drug Events	Type:	Secondary 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:

标本中文名:	咽拭子	组织:	
Sample Name:	Throat swab	Tissue:	
人体标本去向	使用后销毁	说明	
Fate of sample:	Destruction after use	Note:	
标本中文名:	肛拭	组织:	
Sample Name:	Anal swab	Tissue:	
人体标本去向	使用后销毁	说明	
Fate of sample:	Destruction after use	Note:	
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 18 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）:	入组前，研究者再次核对入选及排除标准确认受试者是否入组。研究者关注微信公众号"指南医学"→我的→随机管理→录入受试者信息（按受试者筛选号顺序依次录入）→选择轻症（仅需要吸氧/不吸氧）或重症（需要高流量/无创通气及以上通气支持）→提交自动生成随机号及研究组别（干预组及对照组）。研究医生按照方案要求开医嘱给药治疗。		
Randomization Procedure (please state who generates the random number sequence and by what method):	Prior to enrollment, the researchers rechecked the selection and exclusion criteria to determine if the subjects were enrolled.Researchers pay attention to the WeChat public account "Guide Medicine" → My → Random Management → Enter subject information (entered in the order of the subject's screening number) → C		
UTN(全球唯一识别码):			
盲法:	Open label		
Blinding:	Open label		
试验完成后的统计结果:			
Calculated Results ater the Study Completed:			

研究负责(组长)单位:	
Organizer institution (leader institution):	
资料收集汇总单位:	0
Data collection Institution:	
资料管理单位:	本研究将以CAP-China研究者的名义开展。中心项目协调和数据管理将由北京中日友好医院和北京大学提供。本研究的主要出版物将采用CAP-China研究者的姓名，并向所有协调研究者、研究协调员和机构分配完整的信用凭证。
Data management Institution:	This study will be conducted on behalf of CAP-China researchers. The central project coordination and data management will be provided by Beijing China-Japan Friendship Hospital and Peking University.
资料分析单位:	将由各研究中心接受过培训的工作人员采集所有数据。然后将数据填写在设计的病例报告表（CRF）中，定期由项目组成员录入电子数据库中，并与经验证数据系统中的其他来源提供的数据合并。研究者负责确保录入采集数据的完整、准确与及时记录。然后由项目组对病历中的数据进行审查。按照适用的标准和数据清理程序进行临床数据管理，以确保数据的完整性。
Data analysis Institution:	All data will be collected by staff trained in each research centre. The data is then filled in a designed case report form (CRF), which is regularly entered by the project team members into an electronic database and merged with data from other sources in the validated data system. The investigator is responsible for ensuring that the data entered is complete, accurate, and timely. The project team then reviews the data in the medical records. Manage clinical data in accordance with applicable standards and data cleaning procedures to ensure data integrity.