ChiCTR2100049048 版本V1.2 版本创建时间2022/4/2 3:09:58 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:	ChiCTR2100049048
最近更新时间： Date of Last Refreshed on:	2022/2/27 11:58:17
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：	降尿酸方治疗尿酸性肾病CKD3-4期的随机对照试验
Public title:	A randomized controlled trial evaluating the jiangniaosuan formulation as a treatment for hyperuricemic nephropathy at CKD stages 3-4 patients
注册题目简写：	
Public title acronym:	
研究课题的正式科学名称：	降尿酸方治疗尿酸性肾病CKD3-4期的随机对照试验
Scientific title:	A randomized controlled trial evaluating the jiangniaosuan formulation as a treatment for hyperuricemic nephropathy at CKD stages 3-4 patients
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:	ChiMCTR2100005088

申请注册联系人：	陆黎黎	研究负责人：	高建东
Applicant:	Lu Lili	Study leader:	Gao Jiandong
申请注册联系人电话： Applicant telephone:	+86 18810382712	研究负责人电话： Study leader's telephone:	+86 18101819551
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:	lulilijsrg@163.com	研究负责人电子邮件： Study leader's E-mail:	gaojiandong@hotmail.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：	上海市张衡路528号	研究负责人通讯地址：	上海市张衡路528号
Applicant address:	528 Zhangheng Road, Shanghai	Study leader's address:	528 Zhangheng Road, Shanghai
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：	上海中医药大学附属曙光医院		
Applicant's institution:	Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine		

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:	2021-942-17-01	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：	上海中医药大学附属曙光医院伦理委员会		
Name of the ethic committee:	Ethics Committee of Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine		
伦理委员会批准日期： Date of approved by ethic committee:	2021-04-16		
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：	上海中医药大学附属曙光医院		

Primary sponsor:	Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine
研究实施负责（组长）单位地址:	上海市张衡路528号
Primary sponsor's address:	528 Zhangheng Road, Shanghai

试验主办单位(项目批准或申办者): Secondary sponsor:					
	国家:	中国	省(直辖市):	上海	市(区县):
	Country:	China	Province:	Shanghai	City:
	单位(医院):	上海中医药大学附属曙光医院	具体地址:	张衡路528号	
	Institution hospital:	Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine	Address:	528 Zhangheng Road	

经费或物资来源:	上海市科学技术委员会
Source(s) of funding:	Science and Technology Commission of Shanghai Municipality
研究疾病:	尿酸性肾病慢性肾脏病3-4期
Target disease:	hyperuricemic nephropathy at CKD stages 3-4
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:	通过前瞻性、随机、双盲、安慰剂对照临床研究，明确降尿酸方在痰浊瘀阻型尿酸性肾病CKD3-4期治疗中的临床疗效，证实"化痰祛湿、活血化瘀"的降尿酸方能够有效改善尿酸性肾病CKD3-4期患者的肾功能，延缓进入终末期肾脏病进程，提高患者生活质量，减轻肾脏损伤，减少家庭和社会的负担。并形成有效的尿酸性肾病中医治疗方案，为中医药治疗尿酸性肾病CKD3-4期提供循证医学依据。
Objectives of Study:	Through prospective, randomized, double-blind, placebo-controlled study, the clinical efficacy of Jiangniaosuan formulation in the treatment of phlegm-turbid and stasis-type hyperuricemic nephropathy at CKD stages 3-4 will be confirmed, and the effect of "resolving phlegm and removing dampness, promoting blood circulation and removing blood stasis" will be confirmed. Jiangniaosuan formulation can effectively improve the renal function of hyperuricemic nephropathy at CKD stages 3-4 patients, delay the progression of end-stage renal disease, improve the patient's quality of life, reduce kidney damage, and reduce the burden on family and society. In addition, we look forward to forming an effective TCM method to treat hyperuricemic nephropathy and provide evidence-based medicine for TCM in the treatment of hyperuricemic nephropathy at CKD stages 3-4.
研究设计:	随机平行对照
Study design:	Parallel
纳入标准:	1.符合尿酸性肾病及中医证候诊断标准； 2.年龄18-75岁者，有独立行为能力者，性别不限； 3.肾小球滤过率：15ml/min≤eGFRCKD-EPI-ASIA＜60ml/min； 4.未行肾脏替代治疗； 5.签署进入临床研究知情同意书。
Inclusion criteria	1. Meet the diagnostic criteria for uric acid nephropathy and TCM syndromes; 2. Age 18-75 years old, with independent behavior ability, no gender limitation; 3. Glomerular filtration rate: 15ml/min<=eGFRCKD-EPI-ASIA<60ml/min; 4. No renal replacement therapy; 5. Sign the informed consent to enter the clinical research.
排除标准:	1.对试验药物、对照药物过敏或过敏体质者； 2.妊娠期或哺乳期女性患者； 3.肝功能异常者（ALT或AST超过正常值上限2倍及以上）； 4.合并神经、心血管、消化、泌尿、内分泌和造血系统等严重原发性疾病，精神病患者； 5.正在参加其他临床药物试验者； 6.试验前2周内接受过同类治疗者； 7.尿酸性肾病伴蛋白尿（蛋白尿＞1g/d）或糖尿病或遗传性肾脏疾病患者。
Exclusion criteria:	1. Those with allergies or allergic constitution to the test drugs and control drugs; 2. Pregnant or lactating female patients; 3. Patients with abnormal liver function (ALT or AST exceeds the upper limit of normal by 2 times or more); 4. Combined with serious primary diseases such as nervous, cardiovascular, digestive, urinary, endocrine and hematopoietic systems, mental patients; 5. Those who are participating in other clinical drug trials; 6. Those who have received similar treatment within 2 weeks before the trial; 7. Patients with uric acid nephropathy with proteinuria (proteinuria>1g/d) or diabetes or hereditary kidney disease.
研究实施时间: Study execute time:	从From2020-12-01至To 2023-11-30

干预措施: Interventions:				
	组别:	治疗组	样本量:	59
	Group:	experiment group	Sample size:	
	干预措施:	降尿酸方+非布司他+基础治疗	干预措施代码:	
	Intervention:	Jiangniaosuan formulation+Febuxostat+Basic treatment	Intervention code:	
	组别:	对照组	样本量:	59
	Group:	control group	Sample size:	
	干预措施:	非布司他+基础治疗	干预措施代码:	
	Intervention:	Febuxostat+Basic treatment	Intervention code:	

研究实施地点: Countries of recruitment and research settings:					
	国家:	中国	省(直辖市):	上海	市(区县):
	Country:	China	Province:	Shanghai	City:
	单位(医	上海中医药大学附属曙光医院	单位级别:	三级甲等	

院):

Institution hospital:	Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine	Level of the institution:	Tertiary A

测量指标:
Outcomes:

指标中文名:	尿素氮	指标类型:	次要指标
Outcome:	Blood urea nitrogen	Type:	Secondary indicator
测量时间点:	0,4,12,24周	测量方法:	
Measure time point of outcome:	0,4,12,24 weeks	Measure method:	
指标中文名:	一氧化氮	指标类型:	次要指标
Outcome:	Nitric oxide	Type:	Secondary indicator
测量时间点:	0,24周	测量方法:	
Measure time point of outcome:	0,24 weeks	Measure method:	
指标中文名:	24小时尿尿酸	指标类型:	次要指标
Outcome:	24-hour urine uric acid	Type:	Secondary indicator
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,12,24 weeks	Measure method:	
指标中文名:	24小时尿蛋白定量	指标类型:	次要指标
Outcome:	24-hour urinary protein quantity	Type:	Secondary indicator
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,12,24 weeks	Measure method:	
指标中文名:	尿微量白蛋白肌酐比	指标类型:	次要指标
Outcome:	Urinary microalbumin-creatinine ratio	Type:	Secondary indicator
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,,12,24 weeks	Measure method:	
指标中文名:	尿视黄醇结合蛋白	指标类型:	次要指标
Outcome:	Urinary retinol binding protein	Type:	Secondary indicator
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,,12,24 weeks	Measure method:	
指标中文名:	尿β2-微球蛋白	指标类型:	主要指标
Outcome:	Urinary β2-microglobulin	Type:	Primary indicator
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,12,24 weeks	Measure method:	
指标中文名:	尿N-乙酰-β-D-氨基葡萄糖苷酶	指标类型:	主要指标
Outcome:	Urinary N-acetyl-β-D-glucosaminidase	Type:	Primary indicator
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,12,24 weeks	Measure method:	
指标中文名:	血常规	指标类型:	副作用指标
Outcome:	Blood routine examination	Type:	Adverse events
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,12,24 weeks	Measure method:	
指标中文名:	谷丙转氨酶	指标类型:	副作用指标
Outcome:	Alanine aminotransferase	Type:	Adverse events
测量时间点:	0,12,24周	测量方法:	

Measure time point of outcome:	0,12,24 weeks	Measure method:	
指标中文名:	谷草转氨酶	指标类型:	副作用指标
Outcome:	Aspartate aminotransferase	Type:	Adverse events
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,12,24 weeks	Measure method:	
指标中文名:	γ-谷氨酰转移酶	指标类型:	副作用指标
Outcome:	Gamma-glutamyltransferase	Type:	Adverse events
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,12,24 weeks	Measure method:	
指标中文名:	心电图	指标类型:	副作用指标
Outcome:	Electrocardiogram	Type:	Adverse events
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,12,24 weeks	Measure method:	
指标中文名:	肾脏B超	指标类型:	次要指标
Outcome:	Kidney B ultrasound	Type:	Secondary indicator
测量时间点:	0,24周	测量方法:	
Measure time point of outcome:	0,24 weeks	Measure method:	
指标中文名:	尿常规	指标类型:	副作用指标
Outcome:	Urine routine	Type:	Adverse events
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,12,24 weeks	Measure method:	
指标中文名:	电解质	指标类型:	副作用指标
Outcome:	Electrolyte	Type:	Adverse events
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,12,24 weeks	Measure method:	
指标中文名:	粪便常规	指标类型:	副作用指标
Outcome:	Stool routine	Type:	Adverse events
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,12,24 weeks	Measure method:	
指标中文名:	估算肾小球滤过率	指标类型:	主要指标
Outcome:	Estimated glomerular filtration rate	Type:	Primary indicator
测量时间点:	0,4,12,24周	测量方法:	CKD-EPI公式
Measure time point of outcome:	0,4,12,24 weeks	Measure method:	Chronic Kidney Disease Epidemiology Collaboration equation
指标中文名:	血肌酐	指标类型:	次要指标
Outcome:	Serum creatinine	Type:	Secondary indicator
测量时间点:	0,4,12,24周	测量方法:	酶法
Measure time point of outcome:	0,4,12,24 weeks	Measure method:	enzymatic analysis
指标中文名:	血尿酸	指标类型:	次要指标
Outcome:	Serum uric acid	Type:	Secondary indicator
测量时间点:	0,4,12,24周	测量方法:	化学法
Measure	0,4,12,24 weeks	Measure	chemical method of analysis

time point of outcome:		method:	
指标中文名:	中医证候积分	指标类型:	次要指标
Outcome:	Chinese medicine clinical symptom score	Type:	Secondary indicator
测量时间点:	0,12,24周	测量方法:	
Measure time point of outcome:	0,12,24 weeks	Measure method:	

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

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:	
标本中文名:	尿液	组织:	
Sample Name:	Urine	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:	尚未开始 Pending	年龄范围: Participant age:	最小 Min age 18 岁 years 最大 Max age 75 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）:	由统计人员用SPSS 17.0软件产生随机编码序号，将试验组治疗药与对照组治疗药变为A、B两种组别
Randomization Procedure (please state who generates the random number sequence and by what method):	The statisticians use SPSS 17.0 software to generate random coded serial numbers, and change the treatment drugs of the experiment group and the control group into two groups, A and B.
UTN(全球唯一识别码):	
盲法:	研究者及受试者均采用盲法
Blinding:	The researchers and subjects are blinded
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:	6M
Data collection Institution:	
资料管理单位:	2023年12月公开原始数据
Data management Institution:	In December 2023, open the raw data
资料分析单位:	原始数据记录，病例报告表，采用EpiData Software和SPSS
Data analysis Institution:	Original data records, case report form, using EpiData Software and SPSS