上海中医药大学附属岳阳中西医结合医院医学伦理委员会

IRB of YueYang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of TCM

伦理审查批件

Approval Notice

Approval Number	2019-142
Protocol Title	A Demonstration study on TCM (traditional Chinese medicine) Preventive Treatment of Disease in Patients with Osteoporosis at High Risk
Sponsor	Changchun University of Traditional Chinese Medicine
Research Unit	Yueyang Hospital of Integrated Traditional Chinese and Western Medicine, Shanghai University of Traditional Chinese Medicine
Principle Investigator	Hao Weiwei, Shi Xiao
Review category	Initial review
Type of Review	Meeting review
Review date	December 3, 2019
Reviewer/Secretary	Zheng Li, Wang Xuewen, Liu Weifeng, Huang Jin, Feng Shouquan, Shi Xiao, Fan Minsheng, Ren Li, Yao Yongqi
Documents approved with Version No.	1. Application for initial ethics review 2. Statement of Researcher's Economic Interest 3. Clinical research protocol (version number: V1.0; version date: 2019.11.11) 4. Informed Consent (version number: V1.0; version date: 2019.11.11) 5. Recruitment advertisement (version number: V1.0; version date: 2019.11.11) 6. Case report form (version number: V1.0; version date: 2019.11.11) 7. Subject identification code table 8. Resume and training certificate of main researcher 9. Project mandate

Decision for this proposal

According to the Ministry of Health's Measures for the Ethical Review of Biomedical Research Involving Humans (2016), NMPA's "Good Clinical Drug Quality Management Practices", "Medical Device Clinical Test Management Practices (2016)", WMA "Helsinki Declaration" and CIOMS "Human Bio The ethical principles of the International Moral Guide to Medical Research have been reviewed by this ethics committee and agreed to conduct this research in accordance with the approved clinical research protocol, informed consent, and recruitment materials.

Please follow the GCP principles and follow the protocol approved by the ethics committee to conduct clinical research and protect the health and power of the subjects.

Before the study begins, the applicant is requested to complete the clinical trial registration.

If the main investigator is changed during the research, any amendments to the clinical research protocol, informed consent, recruitment materials, etc., please submit an application for amendment review

If a serious adverse event occurs, the applicant is requested to submit a serious adverse event report.

Please follow the annual / regular follow-up review frequency set by the ethics committee. The applicant should submit a research progress report one month before the deadline; the sponsor should submit a summary report of the research progress of each center to the ethics committee of the group leader unit; Applicants are requested to submit a written report to the ethics committee in a timely manner that affects the progress of the trial or increases the risk of the subject.

The study included subjects who did not meet the inclusion criteria or met the exclusion criteria, met the discontinuation of the trial without withdrawing the subject from the study, were given the wrong treatment or dose, and were given a combination of drugs that were prohibited by the protocol. ; Or may violate the GCP principles, such as adverse effects on the rights / health of the subject and the scientific nature of the research, please submit a report of violation of the protocol to the sponsor / inspector / researcher.

The applicant suspends or terminates the clinical study early, please submit the suspension / termination report in time.

To complete the clinical study, applicants are requested to submit a study completion report.

Continuing review frequency	☐3 months, ☐6 months, ■12 months
The Approval Valid	December 4, 2019——December 3, 2020
Contacts and phone numbers	Secretary of the Ethics Committee: Yin Congquan Tel: 021-65161782-8122
Ethics Committee	上海中医药大学附属岳阳中西医结合医院伦理委员会（盖章） IRB of YueYang Hospital of Integrated Traditional Chinese and Western Medicine,Shanghai University of TCM
Date	December 4, 2019

伦理审查批件

批件号	2019—142
项目名称	骨质疏松高风险人群中医"治未病"干预技术示范研究
申办者	长春中医药大学
研究单位	上海中医药大学附属岳阳中西医结合医院
主要研究者	郝微微、史晓
审查类别	初始审查
审查方式	会议审查
审查日期	2019 年 12 月 3 日
审查委员/秘书	郑　莉、王雪文、刘巍峰、黄　瑾、冯寿全、史　晓、樊民胜、任　力、姚永其
批准文件	1. 初始伦理审查申请 2. 研究者经济利益声明 3. 临床研究方案（版本号：V1.0；版本日期：2019.11.11） 4. 知情同意书（版本号：V1.0；版本日期：2019.11.11） 5. 招募广告（版本号：V1.0；版本日期：2019.11.11） 6. 病例报告表（版本号：V1.0；版本日期：2019.11.11） 7. 受试者身份识别代码表 8. 主要研究者简历、培训证书 9. 项目任务书

审查意见

根据卫生部《涉及人的生物医学研究伦理审查办法》（2016）、CFDA《药物临床试验质量管理规范》、《医疗器械临床试验管理规范（2016）》、WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，同意按所批准的临床研究方案、知情同意书、招募材料开展本项研究。

请遵循 GCP 原则、遵循伦理委员会批准的方案开展临床研究，保护受试者的健康与权利。

研究开始前，请申请人完成临床试验注册。

研究过程中若变更主要研究者，对临床研究方案、知情同意书、招募材料等的任何修改，请申请人提交修正案审查申请。

发生严重不良事件，请申请人及时提交严重不良事件报告。

请按照伦理委员会规定的年度／定期跟踪审查频率，申请人在截止日期前 1 个月提交研究进展报告：申办者应当向组长单位伦理委员会提交各中心研究进展的汇总报告；当出现任何可能显著影响试验进行、或增加受试者危险的情况时，请申请人及时向伦理委员会提交书面报告。

研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止试验规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益／健康以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办者／监察员／研究者提交违背方案报告。

申请人暂停或提前终止临床研究，请及时提交暂停／终止研究报告。

完成临床研究，请申请人提交研究完成报告。

年度/定期跟踪审查频率	□ 3 个月，□ 6 个月，■12 个月
批件有效期	2019 年 12 月 4 日——2020 年 12 月 3 日
联系人与联系电话	伦理委员会秘书：殷从全　　联系电话：021-65161782-8122
主任委员签名	
伦理委员会	上海中医药大学附属岳阳中西医结合医院伦理委员会（盖章）
日期	2019 年 12 月 4 日

会议签到表

伦理委员会名称	上海中医药大学附属岳阳中西医结合医院伦理委员会
会议日期	2019 年 12 月 3 日

姓名	性别	专业背景	签名
郑　莉	女	医　学	
樊民胜	男	社会科学、伦理学	
任　力	男	法　律	
姚永其	男	公　安	
王雪文	女	护理学	
徐玲玲	女	药　学	请假
史　晓	女	医　学	
马晓芃	女	医　学	请假
冯寿全	男	医　学	
孙武权	男	医　学	请假
刘巍峰	男	医　学	
郝微微	女	医　学	请假
黄　瑾	男	药　学	
范　斌	男	医　学	请假
张婷婷	女	医　学	请假
汤　杰	男	医　学	请假

The Institute for Quantitative Social Science
HARVARD UNIVERSITY

February 19, 2020

To Whom it May Concern:

The purpose of this letter is to express support for

Title: A Demonstration study on TCM(traditional Chinese medicine) Preventive Treatment of Disease in Patients With osteoporosis at High Risk

PI: HaO Weiwei, Shi Xiao

The Dataverse Project (dataverse.org) will support the archiving and dissemination of the data stemming from this project. We will provide the PIs with long-term storage and archival preservation for their project. By using the Dataverse, the PIs can share, keep control of, and get recognition for their data through an easy to access web browser interface. Dataverse supports the sharing of research data with a persistent data citation, file-level persistent identifiers, and data publishing and management workflows with versioning and metadata standards. For over a decade, Dataverse has been at the forefront of data publication, citation and preservation. We continue to innovate and expand to more domains, and interoperate with more systems.

The Harvard Dataverse Preservation Policy (https://dataverse.org/best-practices/harvard-dataverse-preservation-policyl) outlines the backup and preservation terms for Harvard Dataverse. The policy is meant to ensure continued access to born digital and digitized data, to ensure their authenticity, and to maintain data quality using the best digital archival practices. Harvard University supports permanent bit-level preservation of all data directly deposited in the Harvard Dataverse.

On top of Harvard University's commitment to archival and long term access of all data published in the Harvard Dataverse, the Harvard Dataverse takes data publication very seriously (see Joint Declaration of Data Citation Principles), encouraging good curation practices through support of standards-based metadata schemas, proper documentation, and automatic extraction of metadata from tabular files to enable data discovery and reuse. Tabular files deposited in the Harvard Dataverse are reformatted into simple open format text files (.tab format) to ensure long-term preservation of the data. Also, once a dataset is published, the repository guarantees archival and long term access to that dataset with a DOI persistent identifier provided by DataCite. The Dataverse is supported by the Harvard University Information Technology team (HUIT), in collaboration with Harvard Library.

We will continue to hold conversations with the PI and the team as the project progresses. The datasets will contain permanent data citations, including checksums, and DOIs, as well as, an Universal Numerical Fingerprint (UNF) (http://guides.dataverse.org/en/latest/developers/unf/unf-v3.html?highlight=unf) for each subsettable data file that is deposited in the dataverse. The data will be curated and cataloged using an extensive list of metadata based on the Data Documentation Initiative (DDI), which will allow the data to be easily described and discovered. The Dataverse will provide everything needed for archiving, sharing, citing, and preserving the data.

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With this letter we indicate our readiness to continue to provide conceptual and technical support for his research. All data files from this dataset will be deidentified according to HIPAA standards prior to being deposited in the Harvard Dataverse Repository, all data files will be restricted for access, and all users of the data will be vetted prior, for approval. We will assist the depositor in creating Terms of Access for this dataset.

Sincerely,

Sonia Barbosa

Sonia Barbosa

Sonia Barbosa
Manager of Curation, Harvard Dataverse
Manager of the Murray Research Archive
Data Science, Harvard University
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