INPLASY PROTOCOL

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Corresponding author:
Hui Su

suhui1334676310@163.com

Author Affiliation:
Shandong University of Traditional Chinese Medicine.

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Conflicts of interest:
None declared.

The efficacy and safety of Tanghuang Jiangu capsule in the treatment osteoporosis: A meta-analysis of randomized controlled trials

Su, H[1]; Xue, H[2]; Wang, H[3]; Tan, G[4]; Yan, B[5]; Xu, Z[6].

Review question / Objective: **In order to more systematically and accurately evaluate the clinical efficacy and safety of Tenghuang Jiangu capsule in the treatment of osteoporosis, we used Meta-analysis to provide more reliable evidence-based medical evidence for the treatment of osteoporosis with traditional Chinese medicine.**
Condition being studied: **At present, Tenghuang Jiangu capsule is widely used in clinical practice to treat spinal diseases and improve osteoporosis.Therefore, in order to more systematically and accurately evaluate the clinical efficacy and safety of Tenghuang Jiangu capsule in the treatment of osteoporosis, we used Meta-analysis to provide more reliable evidence-based medical evidence for the treatment of osteoporosis with traditional Chinese medicine.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 May 2022 and was last updated on 05 May 2022 (registration number INPLASY202250031).

INTRODUCTION

Review question / Objective: **In order to more systematically and accurately evaluate the clinical efficacy and safety of Tenghuang Jiangu capsule in the treatment of osteoporosis, we used Meta-analysis to provide more reliable evidence-based medical evidence for the treatment of osteoporosis with traditional Chinese medicine.**

Rationale: **The search of both domestic and foreign databases including:Medline, Embase,web of science, China National Knowledge Infrastructure (CNKI), Chinese Scientific Journals Database (VIP), Wanfang Database.The database was**

searched from their start date until January 2022. We used the risk of bias assessment tool recommended by Cochrane to evaluate the quality of the included literature and RevMan 5.3 software for data analysis.

Condition being studied: At present, Tenghuang Jiangu capsule is widely used in clinical practice to treat spinal diseases and improve osteoporosis.Therefore, in order to more systematically and accurately evaluate the clinical efficacy and safety of Tenghuang Jiangu capsule in the treatment of osteoporosis, we used Meta-analysis to provide more reliable evidence-based medical evidence for the treatment of osteoporosis with traditional Chinese medicine.

METHODS

Search strategy: The search of both domestic and foreign databases including:Medline, Embase,web of science, China National Knowledge Infrastructure (CNKI), Chinese Scientific Journals Database (VIP), Wanfang Database. retrieval words were“bone ”“osteoporosis” “bone density”“ bone mineral” “tanghuangjiangu”, “ tenghuang jiangu” “ teng-huang-jian-gu” “capsule” “randomized controlled trial”“controlled clinical trial.,with Chinese or English, and both use a combination of subject words and free words. The database was searched from their start date until January 2022.

Participant or population: Participants were patients clinically diagnosed with osteoporosis regardless of gender and origin.

Intervention: Tenghuang Jiangu capsule or combined with other drugs or manual treatment.

Comparator: The control group was treated with traditional Chinese medicine, western medicine and physiotherapy.

Study designs to be included: (1)participants were patients clinically diagnosed with osteoporosis regardless of gender and origin;(2) all were RCT studies; (3) The intervention method of the experimental group is single of Tenghuang Jiangu capsule or combined with other drugs or manual treatment, the control group was treated with traditional Chinese medicine, western medicine and physiotherapy.(4) participants were included in the criteria, diagnostic criteria, and efficacy evaluation criteria were clear;Dual-energy X-ray absorptiometry (DXA) is the gold standard for the diagnosis of osteoporosis. The clinically recommen.

Eligibility criteria: (1)participants were patients clinically diagnosed with osteoporosis regardless of gender and origin;(2) all were RCT studies; (3) The intervention method of the experimental group is single of Tenghuang Jiangu capsule or combined with other drugs or manual treatment, the control group was treated with traditional Chinese medicine, western medicine and physiotherapy.(4) participants were included in the criteria, diagnostic criteria, and efficacy evaluation criteria were clear;Dual-energy X-ray absorptiometry (DXA) is the gold standard for the diagnosis of osteoporosis. The clinically recommended measurement sites are lumbar vertebrae 1–4, total hip, and femoral neck. BMD of T value≤-2.5 can be diagnosed with osteoporosis.

Information sources: The search of both domestic and foreign databases including:Medline, Embase,web of science, China National Knowledge Infrastructure (CNKI), Chinese Scientific Journals Database (VIP), Wanfang Database. retrieval words were“bone ”“osteoporosis” “bone density”“ bone mineral” “tanghuangjiangu”, “ tenghuang jiangu” “ teng-huang-jian-gu” “capsule” “randomized controlled trial”“controlled clinical trial.,with Chinese or English, and both use a combination of subject words and free words. The database was searched from their start date until January 2022.

Main outcome(s): Primary Outcomes:Bone mineral density (BMD) including the lumber, the femoral、 the area of Word triangle.

Additional outcome(s): Secondary Outcomes:Pain assessment:Score of VAS (visual analogue scale). Assessment of joint activity：score of ODI（The Oswestry Disability Index)Biochemical indicators: ALP、BGP、β － CTX、P － PINP、25 －（ OH) VD3; (4)Assessment of Clinical safety : The safety was evaluated through Clinical efficiency, score of Chinese medical syndrome and Adverse event.

Data management: The first screening of the literature of Tenghuang Jiangu capsule initially retrieved in the database for osteoporosis was completed independently by two people in parallel, and it was evaluated by three assessors.

Quality assessment / Risk of bias analysis: The Cochrane Collaboration tool was used to assess the risk of bias of the selected studies[[] Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA; PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;350:g7647. doi: 10.1136/bmj.g7647. Erratum in: BMJ. 2016 Jul 21;354:i4086. PMID: 25555855.]]. The review included whether the random method was described correctly, whether allocation concealment was used, whether the subjects were blinded, whether the outcome evaluators were blinded, whether the study data were complete, whether there were selective reports, and whether there were other biases.The following aspects were assessed independently by two reviewers, random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias.

Strategy of data synthesis: The first screening of the literature of Tenghuang Jiangu capsule initially retrieved in the database for osteoporosis was completed independently by two people in parallel, and it was evaluated by three assessors.

Subgroup analysis: The statistical method used RevMan5.3 software (Cochrane Collaboration, Copenhagen, Denmark) to meta-analyze the data, and the continuous results were expressed as mean difference (MD) with a 95% confidence interval (CI). $p < 0.05$ is considered significant. Heterogeneity is assessed using the I2 test. A fixed-effects model was used when the I2 <50%, and a random-effects model was used when the I2 ≥ 50%. Evaluation publication bias is manifested in the form of funnel charts.

Sensitivity analysis: The statistical method used RevMan5.3 software (Cochrane Collaboration, Copenhagen, Denmark) to meta-analyze the data, and the continuous results were expressed as mean difference (MD) with a 95% confidence interval (CI). $p < 0.05$ is considered significant. Heterogeneity is assessed using the I2 test. A fixed-effects model was used when the I2 <50%, and a random-effects model was used when the I2 ≥ 50%. Evaluation publication bias is manifested in the form of funnel charts.

Country(ies) involved: China.

Keywords: Efficacy, Safety, osteoporosis, Tenghuang Jiangu Capsule, Metaanalysis.

Contributions of each author:

Author 1 - hui su.
Email: suhui1334676310@163.com
Author 2 - haipeng xue.
Author 3 - ruochong wang.
Author 4 - guoqing tan.
Author 5 - binghan yan.
Author 6 - zhanwang xu.