INPLASY PROTOCOL

To cite: Long et al. Efficacy and safety of acupuncture in combination with Chinese herbal medicine in dealing with osteoporosis Protocol for a systematic review and network Meta-analysis. Inplasy protocol 2022110029. doi: 10.37766/inplasy2022.11.0029

Received: 07 November 2022

Published: 07 November 2022

Corresponding author:
Jun Wang

1377600350@qq.com

Author Affiliation:
Acupuncture Department, The First Hospital of Hunan University of Chinese Medicine, China.

Support: **Health Commission Scientific.**

Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

Efficacy and safety of acupuncture in combination with Chinese herbal medicine in dealing with osteoporosis Protocol for a systematic review and network Meta-analysis

Long, P[1]; Zhong, RQ[2]; Zhang, XY[3]; Ju, SC[4]; Wang, J[5].

Review question / Objective: **Population:osteoporosis Intervention:acupuncture combined with Chinese herbal medicine Comparison:acupuncture or Chinese herbal medicine Outcome:primary outcome indicator, and the secondary outcome indicators were lumbar spine bone mineral density (BMD), femoral neck BMD, 1,25-dihydroxyvitamin D3 [1,25-(OH)2D3], serum phosphorus (P) , Alkaline phosphatase (ALP), serum calcium (Ca) and the occurrence of adverse reactions. Study design:RCT.**
Information sources: **Electronic computer search Chinese literature is mainly for China National Knowledge Infrastructure (CNKI), VIP, Wanfang and China Biomedical Literature Database (CBM). English literatures were searched through PubMed, EMbase, and Cochrane Library. The words "acupuncture", "Chinese herbal medicine", "osteoporosis" and their synonyms were used as search terms, and the search time was from the establishment of the database to November 2022. Taking PubMed as an example.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 November 2022 and was last updated on 12 November 2022 (registration number INPLASY2022110029).

INTRODUCTION

Review question / Objective: **Population:osteoporosis Intervention: acupuncture combined with Chinese herbal medicine Comparison:acupuncture or Chinese herbal medicine Outcome:primary outcome indicator, and the secondary outcome indicators were lumbar spine bone mineral density (BMD), femoral neck BMD, 1,25-dihydroxyvitamin D3 [1,25-(OH)2D3], serum phosphorus (P) , Alkaline**

phosphatase (ALP), serum calcium (Ca) and the occurrence of adverse reactions. Study design:RCT.

Condition being studied: Osteoporosis (OP) is a systemic metabolic bone disease caused by multiple causes, with a high prevalence, unknown pathogenesis, and lack of specific preventive and therapeutic drugs, and thus has become an important global public health problem. The incidence of OP is highly correlated with age [1]. In recent years, with the aging of the world population, the incidence of OP has increased significantly, with about 200 million OP patients worldwide [2]. At the same time, OP patients are very prone to fragility fractures--osteoporotic fractures, which can cause complications such as infection and thrombosis, and even lead to disability and death of patients, seriously affecting the quality of life of patients [3, 4]. Disturbances in the homeostasis of bone remodeling are the underlying cause of OP. Bone remodeling is a physiological process in which osteoblasts form new bone and osteoclasts resorb the original bone matrix, which is a key process in maintaining healthy bone tissue in adults, and multiple factors are involved in regulating this process [5]. Bisphosphonates, estrogens, and raloxifene are commonly used to treat OP by reducing the number of osteoclasts, inhibiting bone resorption, slowing bone loss, and maintaining bone health [6]. Although these drugs significantly increase bone mass, they have limitations and side effects, such as suboptimal efficacy in a large number of patients, thromboembolism and gastrointestinal irritation [7-8]. Therefore, it is necessary to find new drugs to improve OP while minimizing side effects

METHODS

Participant or population: Osteoporosis patient.

Intervention: Acupuncture combined with Chinese herbal medicine.

Comparator: Acupuncture or Chinese herbal medicine.

Study designs to be included: This study collect all randomized controlled trials on acupuncture combined with CHM in the treatment of OP patients, regardless of their blinding, publication status or location, conducted in Chinese and English only.

Eligibility criteria: Types of research: This study collect all randomized controlled trials on acupuncture combined with CHM in the treatment of OP patients, regardless of their blinding, publication status or location, conducted in Chinese and English only. Research objects: For patients with a definite diagnosis of OP, there are no restrictions on the nationality, race, gender, age, occupation, course of disease and onset time of the patient.2.3.3 InterventionsThe control group was treated with acupuncture or CHM, and the treatment group was treated with acupuncture combined with CHM. The dosage form, dosage and course of treatment of CHM were not limited. Outcome indicators: The total effective rate of clinical efficacy was the primary outcome indicator, and the secondary outcome indicators were lumbar spine bone mineral density (BMD), femoral neck BMD, 1,25-dihydroxyvitamin D3 [1,25-(OH)2D3], serum phosphorus (P) , Alkaline phosphatase (ALP), serum calcium (Ca) and the occurrence of adverse reactions.

Information sources: Electronic computer search Chinese literature is mainly for China National Knowledge Infrastructure (CNKI), VIP, Wanfang and China Biomedical Literature Database (CBM). English literatures were searched through PubMed, EMbase, and Cochrane Library. The words "acupuncture", "Chinese herbal medicine", "osteoporosis" and their synonyms were used as search terms, and the search time was from the establishment of the database to November 2022. Taking PubMed as an example.

Main outcome(s): The total effective rate of clinical efficacy was the primary outcome indicator, and the secondary outcome indicators were lumbar spine bone mineral density (BMD), femoral neck BMD, 1,25-

dihydroxyvitamin D3 [1,25-(OH)2D3], serum phosphorus (P) , Alkaline phosphatase (ALP), serum calcium (Ca) and the occurrence of adverse reactions.

Quality assessment / Risk of bias analysis: The quality of the literature was evaluated according to the Cochrane 5.0.1 Manual of Systematic Review, from the six aspects of randomization method, allocation concealment, blinding, completeness of data results, selective reporting of research results and other factors that may potentially affect the authenticity. The quality of the literature was evaluated at three levels: "high" (high bias) and "unclear" (lack of relevant information or uncertain bias).

Strategy of data synthesis: Perform network meta-analysis based on Bayesian model, merge and compare the direct evidence and indirect evidence of the included studies, use R4.0.2 software and Ge MTC to establish 4 chains for simulation, the number of iterations is set to 5000 times, and the first 20000 times use For annealing to remove the effect of the initial value, the step size is set to 10. The Brooks-Gelman Rubin diagnostic method was used to judge the degree of model convergence, that is, the median value of the reduction factor after iteration and 97.5% tended to 1 and reached stability after iterative calculation, indicating that the degree of model convergence was satisfactory. In addition, Stata 16.0 software was used to calculate and draw the area under the cumulatve rnking curve (SUCRA) to intuitively reflect the relative pros and cons of efficacy and safety between drugs. The value of SUCRA ranges from 0 to 1, and the higher the value of SUCRA Larger means better curative effect.

Subgroup analysis: None reported.

Sensitivity analysis: Sensitivity analysis was performed on the included indicators The results of the new Meta-analysis, in which a certain RCT was excluded one by one, were were unchanged, which proved that the results of Meta-analysis were relatively stable.

Country(ies) involved: China.

Keywords: acupuncture, Chinese herbal medicine, osteoporosis, systematic review, network meta-analysis, protocol.

Contributions of each author:
Author 1 - Piao Long.
Email: longpiao0908@163.com
Author 2 - Ruqian Zhong.
Email: 2449858901@qq.com
Author 3 - Xinyue Zhang.
Email: 3570548930@qq.com
Author 4 - Shicong Ju.
Email: jushicongtcm@126.com
Author 5 - Jun Wang.
Email: 1377600350@qq.com