INPLASY PROTOCOL

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None declared.

Jintiange Capsule May Have a Positive Effect in OVCF Patients with percutaneous vertebral augmentation: A Meta-Analysis of Randomized Trials

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Review question / Objective: **We aimed to conduct a meta-analysis of the effects of JTG capsules on patients with OVCF underwent PVA surgery, focusing on clinical outcomes and drug safety.**
Condition being studied: **This meta-analysis aims to systematic evaluation of clinical efficacy and adverse effects of JTG with PVA in the treatment of osteoporotic vertebral compression fracture (OVCF).Our current evidence suggests that JTG capsule may relieve pain in OVCF patients who underwent PVA surgery, improve functional activity, and increase BMD, particularly in patients under the age of 70, as well as increase BGP levels.However, considering the unsatisfactory quality of the included trials, more high-quality trials are needed to prove this issue.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 September 2022 and was last updated on 08 September 2022 (registration number INPLASY202290038).

INTRODUCTION

Review question / Objective: **We aimed to conduct a meta-analysis of the effects of JTG capsules on patients with OVCF underwent PVA surgery, focusing on clinical outcomes and drug safety.**

Rationale: **Our current evidence suggests that JTG capsule may relieve pain in OVCF patients who underwent PVA surgery, improve functional activity, and increase BMD, particularly in patients under the age of 70, as well as increase BGP levels.However, considering the unsatisfactory quality of the included trials,**

more high-quality trials are needed to prove this issue.

Condition being studied: This meta-analysis aims to systematic evaluation of clinical efficacy and adverse effects of JTG with PVA in the treatment of osteoporotic vertebral compression fracture (OVCF).Our current evidence suggests that JTG capsule may relieve pain in OVCF patients who underwent PVA surgery, improve functional activity, and increase BMD, particularly in patients under the age of 70, as well as increase BGP levels.However, considering the unsatisfactory quality of the included trials, more high-quality trials are needed to prove this issue.

METHODS

Search strategy: Two researchers systematically conducted electronic searches in the following databases: PubMed, Cochrane Library, EMBASE, Web of Science database, Chinese Biomedical Database (CBM), Chinese VIP Information, China National Knowledge Infrastructure (CNKI), and WanFang, while the searches were accomplished from the inception of each database to 1 June 2022. During the process, if the two researchers disagree, the third researcher would make the decision. The search strategy of PubMed was as follows, and we adjusted it when searching other Chinese or English databases: (jintiange capsule OR jintian ge capsule OR jintiange jiaonang OR jin tian ge jiaonang OR artificial tiger powder) AND (bone Density OR musculoskeletal diseases OR osteoporotic vertebral compression fracture OR osteoporosis). The two researchers also manually searched the reference lists of all identified articles for possible related studies to supplement the relevant literature. Integration and deletion of duplicate trials were performed on the EndNote software.

Participant or population: Studies were included in the analysis if the following inclusion criteria were met: (1) study design: randomized controlled study; (2) study population: participants were patients with OVCFs; (3) purpose of interventions: to compare clinical outcome differences between JTG capsule combined with other drugs or therapies after the percutaneous vertebroplasty; (4) outcome measurements: the study reported at least one of the following outcomes: the total effective rate, the VAS score, ODI, BMD, adverse, and BGP. Studies that did not meet the above criteria were excluded from selection.

Intervention: The experimental group was treated with JTG capsule alone or combined with conventional medication for intervention. The treatment dose was three times a day and three capsules each time, and the treatment duration was four to twelve weeks. The control group was treated with conventional Western medicine.

Comparator: The experimental group was treated with JTG capsule alone or combined with conventional medication for intervention. The treatment dose was three times a day and three capsules each time, and the treatment duration was four to twelve weeks. The control group was treated with conventional Western medicine.

Study designs to be included: A meta-analysis of clinical randomized controlled trials (RCTs) on JTG capsule treatment was carried out in OVCF patients who underwent PVA surgery. The search time was from the establishment of the database to 1 June 2022. The database included PubMed, Cochrane Library, EMBASE, Web of Science database, Chinese Biomedical database (CBM), Chinese VIP information, China National Knowledge Infrastructure (CNKI), and WanFang database. The outcome indicators were extracted from the included literature and analyzed, and the risk of bias was assessed through Cochrane Handbook 5.0.1.

Eligibility criteria: Studies were included in the analysis if the following inclusion criteria were met: (1) study design: randomized controlled study; (2) study population: participants were patients with

OVCFs; (3) purpose of interventions: to compare clinical outcome differences between JTG capsule combined with other drugs or therapies after the percutaneous vertebroplasty; (4) outcome measurements: the study reported at least one of the following outcomes: the total effective rate, the VAS score, ODI, BMD, adverse, and BGP. Studies that did not meet the above criteria were excluded from selection.

Information sources: PubMed, Cochrane Library, EMBASE, Web of Science database, Chinese Biomedical Database (CBM), Chinese VIP Information, China National Knowledge Infrastructure (CNKI), and WanFang, while the searches were accomplished from the inception of each database to 1 June 2022.

Main outcome(s): The total effective rate, the VAS score, ODI, BMD, adverse, and BGP.

Quality assessment / Risk of bias analysis: Two reviewers determined study eligibility independently. A third investigator was involved to reach an agreement. Relevant information was extracted from studies, included: (1) the title; (2) authors; (3) year of publication; (4) sample size; (5) gender; (6) type of intervention; (7) surgical approach; (8) duration of the follow-up.

Strategy of data synthesis: All the meta-analyses were performed with the Review Manager software (RevMan Version 5.4 Cochrane Collaboration). Heterogeneity was tested using Chi square test and quantified by calculating I2 statistic, for which $P < 0.05$ and $I2 > 50$ % was defined as high heterogeneity and assessed by the random-effects model. When the chi-squared test P value was >0.05 and I2 tests value was ≤50%, it was defined as an acceptable heterogeneity data and assessed by the fixed-effects model. For the pooled effects, mean difference (MD) or standard mean difference (SMD) was calculated for continuous variables according to the consistency of measurement units, and relative ratio (RR) was calculated for dichotomous variables. Continuous outcomes are presented as mean differences and 95 % confidence intervals (CI), whereas dichotomous outcomes are presented as relative risk and 95 % CI.

Subgroup analysis: Subgroup analysis of VAS scores was performed for the mean baseline of the follow-up 3 month and more than 3 months. In 2 studies , follow-up time baseline levels were 3 months, which in the remaining 5 studies were, respectively, 12 months ,6months, 12 months, 6months and 6months.Subgroup analysis of BMD of the lumbar vertebrae was performed for the mean baseline of age≥70 and <70. In 3 studies , age baseline levels were, respectively, 65.88, 67 and 68.8, which in the remaining 6 studies were all higher than 70.

Sensitivity analysis: The heterogeneity of VAS scores (I2=97%), ODI scores (I2=94%), BMD of the lumbar vertebrae (I2=97%), BMD of the femoral neck (I2=80%) and BGP (I 2=94%) level is high.

Country(ies) involved: China.

Keywords: Jintiange Capsule, vertebral compression fractures, Randomized Trials, Meta-analysis, osteoporosis, vertebral augmentation.

Contributions of each author:

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