INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The efficacy of Cerus and Cucumis Polypeptide injection combined with Bisphosphonates on postmenopausal women with osteoporosis: A protocol for systematic review and meta-analysis

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Review question / Objective: **The aim of this review is to evaluate the effectiveness of Cerus and Cucumis Polypeptide injection combined with Bisphosphonates for postmenopausal osteoporosis.**
Condition being studied: **Postmenopausal osteoporosis (PMOP) is a disorder of bone metabolism caused by estrogen deficiency in women after menopause, which manifests clinically as pain, spinal deformities and even fragility fractures, affecting the quality of life of patients and possibly shortening their life span. Bisphosphonates are commonly used to control and delay the progression of the disease, improve the patient's symptoms and reduce the incidence of fragility fractures. However, single drugs are still lacking in controlling the progression of the disease, and the combination of drugs is the clinical priority.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 May 2022 and was last updated on 11 May 2022 (registration number INPLASY202250067).

INTRODUCTION

Review question / Objective: **The aim of this review is to evaluate the effectiveness of Cerus and Cucumis Polypeptide injection combined with Bisphosphonates for postmenopausal osteoporosis.**

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METHODS

Search strategy: CNKI, Wanfang, VIP, CBM, PubMed, Embase and Cochrane Library databases were searched for this study.Take the subject terms combined with free words to search,take PubMed as an example:terms consist of (osteoporosis OR postmenopausal osteoporosis) AND (cerus and cucumis polypeptide injection OR Bisphosphonates OR Alendronate sodium OR Ibandronate Monosodium OR Etidronate Disodium Tablets OR Clodronic acid OR Zoledronic acid OR Risedronate Sodium) AND (randomized controlled trial OR controlled clinical trial OR random trials).

Participant or population: Patients were diagnosed with postmenopausal osteoporosis and the study belongs to randomized controlled trial.Clinical results included Lumbar vertebral and Femoral neck bone density(dual-energy X-ray absorptiometry);visual analog pain (VAS) score; Serum bone metabolic markers; incidence of fragility fractures; Quality of life and adverse effects.Experimental group must cover Cerus and Cucumis Polypeptide injection combined with Bisphosphonates.Otherwise,studies will be excluded if they cannot meet the inclusion criteria.

Intervention: Intervention of the experimental group must cover Cerus and Cucumis Polypeptide injection combined with Bisphosphonates.If both the experimental and control groups have received conventional treatment, the conventional treatment must be consistent. The duration of treatment should be at least half a year.

Comparator: The control group must have no treatment, received placebo or routine treatment alone.

Study designs to be included: The control group must have no treatment, received placebo or routine treatment alone.

Eligibility criteria: Randomized clinical trials will be included irrespective of blinding, publication status or language.

Information sources: We will search articles in seven electronic database including: CNKI, Wanfang, VIP, CBM, PubMed, Embase and Cochrane Library databases. All the publications, with no time restrictions, will be searched without any restriction of countries or article type. Reference list of all selected articles will independently screened to identify additional studies left out in the initial sea. Randomized clinical trials will be included irrespective of blinding, publication status or language.

Main outcome(s): The primary outcome is Lumbar vertebral and Femoral neck bone density(dual-energy X-ray absorptiometry).

Additional outcome(s): The secondary outcome are visual analog pain (VAS) score; Serum bone metabolic markers; incidence of fragility fractures; Quality of life and adverse effects.

Data management: (1)NoteExpress and Excel software will be used to extract data,and the content will be stored in electronic chart. (2)Different researchers will separately screen the titles and abstracts of records acquiaed potential eligibility which comes from the electronic databases.Full texts screening and data extraction will be conducted afterwards independently.Any disagreement will be resolved by discussion until consensus is reached or by consulting a third author.In this step, we will use NoteExpress.(3)The following data will be extracted: author, year of publication, country , interventions of experimental groups and control groups,time point,outcome measures,age of patients,total number of people included

in the study,patients' basic information, etc. Different researchers will separately extract data. Any disagreement regarding data extraction will be will be resolved by discussion until consensus is reached or by consulting a third author. In this step, we will use Excel.

Quality assessment / Risk of bias analysis: Two reviewers will independently assesses the quality of the selected studies according to the Cochrane Collaboration's tool for randomized controlled trials.Items will be evaluated in three categories:Low risk of bias, unclear bias and high risk of bias.The following characteristics will be evaluated:random sequence generation (selection Bias), allocation concealment (selection bias), blinding of participants and personnel(performance bias), incomplete outcome data(attrition bias), selective reporting(reporting bias)and other biases. Results from these questions will be graphed and assessed using Review Manager 5.4. The results will be presented in the form of a graph, and will be independently evaluated by two researchers.If there are differences of opinion, they will be discussed with the third researcher.

Strategy of data synthesis: Statistical analysis will be conducted using RevMan 5.4 software.For continuous data, will be used mean difference (MD) as the effect indicator with 95% confidence interval,and dichotomous data will be calculated as risk ratio (RR) or odds ratio (OR)as the effect index with 95% confidence interval.If the studies with no statistical homogeneity,the fixed-effect model can be used for analysis; if the studies with significant statistical heterogeneity,random effects model analysis will be used.

Subgroup analysis: We will perform a subgroup analysis based on the type of anti-osteoporosis drug; and a subgroup analysis based on the duration of the disease.

Sensitivity analysis: We will perform a subgroup analysis based on the type of anti-osteoporosis drug; and a subgroup analysis based on the duration of the disease.

Language: We will perform a subgroup analysis based on the type of anti-osteoporosis drug; and a subgroup analysis based on the duration of the disease.

Country(ies) involved: China.

Keywords: postmenopausal osteoporosis; cerus and cucumis polypeptide injection; bisphosphonates ; protocol.

Dissemination plans: We plan to publish a systematic review based on this protocol.

Contributions of each author:

Author 1 - Kemeng Xiang - Drafted and improved the manuscript.
Email: 251204100@qq.com
Author 2 - Huiming Hou - Revise this protocol; search strategy; analysis of results.
Author 3 - Ming Zhou - data collection.