INPLASY PROTOCOL

To cite: Tang et al. Efficacy of alendronate for the treatment of ankylosing spondylitis: a protocol for systematic review and meta-analysis. Inplasy protocol 202040153. doi: 10.37766/inplasy2020.4.0153

Received: 23 April 2020

Published: 23 April 2020

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Support: **SRPHLJPDH (2018143)**

Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest: **No.**

Efficacy of alendronate for the treatment of ankylosing spondylitis: a protocol for systematic review and meta-analysis

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Review question / Objective: **Is alendronate effective and safety for the treatment of patients with AS?**
Condition being studied: **Ankylosing spondylitis; alendronate.**
Information sources: **Electronic databases search Two authors will carry out a comprehensive literature search from the below electronic databases: PubMed, EMBASE, Cochrane Library, Web of Science, Allied and Complementary Medicine Database, WANGFANG, and China National Knowledge Infrastructure. All these electronic databases will be searched from their commencement to the January 31, 2020 without language and publication status limitations. Any potential randomized controlled trials (RCTs) that exploring the efficacy and safety of alendronate for the treatment of patients with AS will be included. An example of detailed search strategy for PubMed is presented. We will also modify similar search strategies for other electronic databases. Other literature sources search We will also search other literature resources, such as Google Scholar, websites of clinical trial registry, dissertations, and reference lists of included trials.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 April 2020 and was last updated on 23 April 2020 (registration number INPLASY202040153).

INTRODUCTION

Review question / Objective: **Is alendronate effective and safety for the treatment of patients with AS?**

Condition being studied: **Ankylosing spondylitis; alendronate.**

METHODS

Participant or population: **Any adult participants (more than 18 years old) with a definite diagnosis of AS will be included in spite of their race, gender, educational background, and duration of AS.**

Intervention: The experimental intervention must be alendronate.

Comparator: The control intervention could be any treatments, such as placebo, other medications, and alternative therapies. However, we will exclude studies using any types of alendronate, including its combination with other managements as their comparators.

Study designs to be included: This study will only include randomized controlled trials (RCTs) of alendronate for the treatment of patients with AS.

Eligibility criteria: This study will only include RCTs of alendronate for the treatment of patients with AS. Besides RCTs, we will exclude any other studies, such as non-clinical trials, non-RCTs, and quasi-RCTs.

Information sources: Electronic databases search Two authors will carry out a comprehensive literature search from the below electronic databases: PubMed, EMBASE, Cochrane Library, Web of Science, Allied and Complementary Medicine Database, WANGFANG, and China National Knowledge Infrastructure. All these electronic databases will be searched from their commencement to the January 31, 2020 without language and publication status limitations. Any potential randomized controlled trials (RCTs) that exploring the efficacy and safety of alendronate for the treatment of patients with AS will be included. An example of detailed search strategy for PubMed is presented. We will also modify similar search strategies for other electronic databases. Other literature sources search We will also search other literature resources, such as Google Scholar, websites of clinical trial registry, dissertations, and reference lists of included trials.

Main outcome(s): Primary outcome - Bone densitometry (as reported in the trials by any instruments or tools). Secondary outcomes - Pain intensity (as reported in the trial by any pain scales), Quality of life (as reported in the trial by any tools, such as Ankylosing Spondylitis Quality of Life questionnaire), Disease activity (as reported in the trial by any indexes, such as Bath Ankylosing Spondylitis Disease Activity Index), Functional status (as reported in the trial by any scores, such as Bath Ankylosing Spondylitis Functional Index), Adverse events.

Data management: Two authors will independently extract the data from each included trial in accordance with the predefined data collection form. Any uncertainties will be resolved by another author and a consensus will be reached finally. The collected information is as follows: Study details: title, first author, publication date, location, et al. Study methods: randomization specifics, blinding, allocation, follow-up information, et al. Patient characteristics: age, sex, sample size, duration and severity of AS, et al. Intervention and control details: treatment duration, dosage, frequency, et al. Outcomes: outcome measurements reported in the trial, adverse events, et al. Others: funding information, conflict of interest, et al.

Quality assessment / Risk of bias analysis: Study quality of each included trial will be evaluated by two independent authors using Cochrane risk of bias tool, which examines 7 domains. We will rate each source of bias as low, unclear or high. Any different views will be worked out with the help of another author through discussion.

Strategy of data synthesis: RevMan 5.3 software will be employed for all data analysis and meta-analysis if possible. I^2 test will be used for heterogeneity identification. $I^2 \leq 50\%$ suggests reasonable heterogeneity, and a fixed-effect model will be exerted. Otherwise, $I^2 > 50\%$ means substantial heterogeneity, and a random-effect model will be employed. If ample data is extracted from sufficient trials with low heterogeneity, we will carry out meta-analysis to explain the results. On the other hand, we will perform subgroup analysis and sensitivity analysis to test possible sources of significant heterogeneity. If

meta-analysis is deemed not to be conducted, we will elaborate study results using a narrative summary.

Subgroup analysis: Subgroup analysis will be developed to investigate the possible sources of significant heterogeneity according to the characteristics of study, types of intervention and controls, and different outcome measurements.

Sensibility analysis: A sensitivity analysis will be carried out to test the robustness and stability of pooled results by taking away low quality trials or trials reporting data missing.

Country(ies) involved: China.

Keywords: Ankylosing spondylitis; alendronate; efficacy; safety.