

INPLASY PROTOCOL

To cite: Liu. Efficacy and safety of sulfasalazine for the treatment of ankylosing spondylitis: A systematic review and meta-analysis. Inplasy protocol 202240053. doi: 10.37766/inplasy2022.4.0053

Received: 09 April 2022

Published: 09 April 2022

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Author Affiliation:
Not reported.

Support: None.

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

Conflicts of interest:
None declared.

Efficacy and safety of sulfasalazine for the treatment of ankylosing spondylitis: A systematic review and meta-analysis

Liu, HF¹.

Review question / Objective: Is sulfasalazine effective and safe for the treatment of ankylosing spondylitis(AS)?

Condition being studied: Sulfasalazine; ankylosing spondylitis.
Study designs to be included: Only randomized controlled trials (RCTs) and case-control studies assessing the effectiveness and safety of sulfasalazine for AS will be included. We will exclude any other studies, such as non-clinical trials, case reports, and case series.

Information sources: We will search the databases of Cochrane Library, EMBASE, PubMed, Web of Science, China National Knowledge Infrastructure and Wanfang Data.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 April 2022 and was last updated on 09 April 2022 (registration number INPLASY202240053).

INTRODUCTION

Review question / Objective: Is sulfasalazine effective and safe for the treatment of ankylosing spondylitis(AS)?

Condition being studied: Sulfasalazine; ankylosing spondylitis.

METHODS

Search strategy: We will search the databases of Cochrane Library, EMBASE, PubMed, Web of Science, China National Knowledge Infrastructure and Wanfang Data from the inception to the April 1, 2022. The language is limited to Chinese and English. Reference lists of included studies

will also be checked to identify any potential eligible trials.

Participant or population: Patients clinically diagnosed of AS will be included without restrictions of race, sex, and age.

Intervention: Any included studies for evaluating the effectiveness and safety of sulfasalazine only for patients with AS will be included.

Comparator: The control interventions can be the placebo, medications, and so on, except the sulfasalazine.

Study designs to be included: Only randomized controlled trials (RCTs) and case-control studies assessing the effectiveness and safety of sulfasalazine for AS will be included. We will exclude any other studies, such as non-clinical trials, case reports, and case series.

Eligibility criteria: Data extraction will be independently performed by two authors using a predefined standardized data extraction sheet. The following information will be extracted: first author, published year, location, study design and methods, interventions, outcomes, and any other reporting information. A third author will be invited as an arbiter if divergences occur between the two authors.

Information sources: We will search the databases of Cochrane Library, EMBASE, PubMed, Web of Science, China National Knowledge Infrastructure and Wanfang Data.

Main outcome(s): The primary outcome includes duration of morning stiffness, severity of morning stiffness, pain intensity, erythrocyte sedimentation rate and IgA. The secondary outcomes comprise functional status, quality of life, and psychological outcomes.

Additional outcome(s): Adverse events are also assessed.

Quality assessment / Risk of bias analysis: Risk of bias assessment will be evaluated

by using the criteria as described in details of the Cochrane Handbook of Systematic Review of Interventions. Two authors will independently evaluate each included study, with a third author acting as an arbiter through discussion if any differences regarding the risk of bias assessment arise.

Strategy of data synthesis: Outcome data will be pooled by using fixed-effect model with acceptable heterogeneity. Otherwise, we will use random-effect model to pool the data, and we will also perform subgroup analysis. We will not consider pooling the data if the heterogeneity is still substantial after the subgroup analysis.

Subgroup analysis: We will conduct the subgroup analysis when the heterogeneity is not acceptable. It will be performed according to the different treatments, controls, outcome tools.

Sensitivity analysis: Sensitivity analysis can be considered in the whole implementation process. The specific analysis methods should be selected and implemented according to the specific conditions of the implementation of meta analysis.

Language: English.

Country(ies) involved: China.

Keywords: sulfasalazine; ankylosing spondylitis; meta-analysis.

Contributions of each author:
Author 1 - Hong-fei Liu.