

INPLASY PROTOCOL

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Corresponding author:
Can Chen

allwichen@163.com

Author Affiliation:
Hangzhou First People's
Hospital

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Conflicts of interest:
None.

Huanglian Jiedu Decoction for treatment of multiple myeloma: a protocol for a systematic review and meta-analysis

Chen, C¹.

Review question / Objective: P: Patients suffering from multiple myelomas I: Huanglian Jiedu Decoction, C: Any intervention measures not including Huanglian Jiedu Decoction, O: Progression-free survival(PFS), Overall Response Rate(ORR), Adverse event(AE), S: Randomized controlled trials.

Condition being studied: Huanglian Jiedu Decoction; multiple myeloma; meta-analysis.

Information sources: Relevant literature will be retrieved by electronically searching the following data sources: MEDLINE (by Pubmed), Embase, Cochrane Library, ClinicalTrials.gov databases, Chinese National Knowledge Infrastructure Database (CNKI), wanfang database, China Biology Medicine(CBM) and VIP database. There were no limits on study dates, language, publication type, or status.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 June 2020 and was last updated on 25 June 2020 (registration number INPLASY202060094).

INTRODUCTION

Review question / Objective: P: Patients suffering from multiple myelomas I: Huanglian Jiedu Decoction, C: Any intervention measures not including Huanglian Jiedu Decoction, O:

Progression-free survival(PFS), Overall Response Rate(ORR), Adverse event(AE), S: Randomized controlled trials.

Condition being studied: Huanglian Jiedu Decoction; multiple myeloma; meta-analysis.

METHODS

Participant or population: Patients with multiple myelomas.

Intervention: Huanglian Jiedu Decoction.

Comparator: Any intervention measures not including Huanglian Jiedu Decoction.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: (1) randomized controlled trial; (2) type of participants must be patients with symptomatic diagnosed MM; (3) Huanglian Jiedu Decoction (including Huanglian Jiedu Decoction only and other treatments with Huanglian Jiedu Decoction) must be used for intervention. (4) control group is not restricted, but Huanglian Jiedu Decoction is not included. (5) the primary outcomes include the following: progression-free survival, overall response rate, adverse event.

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Main outcome(s): Progression-free survival(PFS).

Additional outcome(s): Overall Response Rate(ORR), Adverse event(AE).

Quality assessment / Risk of bias analysis: We assessed the risk of bias of RCTs in this review using the Cochrane Collaboration Risk of Bias Tool provided by RevMan 5.3 software (Figure 2).[20] And risk of bias is assessed according to the Cochrane Handbook. For included study, types of bias are divided into 3 levels: low, unclear, high. 2 authors independently assess the risk of bias of the included studies. The authors resolve any disagreements by

discussion, including input from a third independent review author if required.

Strategy of data synthesis: The dichotomous data is expressed as the relative risk (RR). And the mean difference (MD) or standardized mean difference will be used to assess the difference in the continuous outcomes between the groups. Statistical heterogeneity across the included studies will be examined using the I^2 statistic. Then, the authors will determine if there is a possibility of performing a meta-analysis. If $I^2 > 85\%$, the quantitative analysis will only be used. And with an $85\% > I^2 > 50\%$ regarded as being indicative of the possibility of statistical heterogeneity, resulting in the selection of a random-effects model for merging of results. Otherwise, the fixed-effects model will be selected.

Subgroup analysis: If the necessary data are available, subgroup analyses will be performed.

Sensibility analysis: If the necessary data are available, subgroup analyses will be performed.

Country(ies) involved: China.

Keywords: Huanglian Jiedu Decoction, multiple myeloma, meta-analysis.

Contributions of each author:
Author 1 - Can Chen.