INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy and safety of Baitouweng decoction in the treatment of radiation proctitis: A Systematic Review and Network Pharmacology-Based Identification

Wu, Z[1]; Yin, B[2]; Yang, Z[3].

Review question / Objective: **P:Patients diagnosed with radiation proctitis using clearly defined or internationally recognized criteria, irrespective of gender, age and ethnicity. I:The treatment group was treated with BTWD alone or with adjuvant therapy, including BTWD plus other therapy. C:Participants in the control group were being treated with placebo or other therapy alone. O:Clinical efficacy, TCM syndrome score, survival rate. S:Randomized controlled trials.**
Condition being studied: **Baitouweng decoction in the treatment of radiation proctitis.**
Information sources: **We searched Englishand Chinese-language databases and followed the methods outlined in the Cochrane Handbook of Systematic Reviews. English-language databases included PubMed, Excerpta Medica Database (Embase), Cochrane Central Register of Controlled Trials (CENTRAL), including the Cochrane Library, and Allied and Complementary Medicine Database (AMED); Chinese-language databases included China SinoMed, China National Knowledge Infrastructure (CNKI), Chongqing VIP (CQVIP), and Wanfang Databases were searched from inception to SeptemberMarch 2021. No restrictions were applied.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 September 2021 and was last updated on 17 September 2021 (registration number INPLASY202190053).

INTRODUCTION

Review question / Objective: **P:Patients diagnosed with radiation proctitis using clearly defined or internationally recognized criteria, irrespective of gender, age and ethnicity. I:The treatment group was treated with BTWD alone or with adjuvant therapy, including BTWD plus other therapy. C:Participants in the control group were being treated with placebo or other therapy alone. O:Clinical efficacy,**

TCM syndrome score, survival rate. S:Randomized controlled trials.

Condition being studied: Baitouweng decoction in the treatment of radiation proctitis.

METHODS

Participant or population: Patients diagnosed with radiation proctitis using c l early defined or internationally recognized criteria, irrespective of gender, age and ethnicity.

Intervention: The treatment group was treated with BTWD alone or with adjuvant therapy, including BTWD plus other therapy.

Comparator: Participants in the control group were being treated with placebo or other therapy alone.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: 1.Participants: Patients diagnosed with radiation proctitis using clearly defined or internationally recognized criteria, irrespective of gender, age and ethnicity. 2. Type of Interventions: The treatment group was treated with Baitouweng decoction alone or with adjuvant therapy, including Baitouweng decoction plus other therapy.3. The guide recommends a placebo, lifestyle intervention or routine therapy (including ADA and Chinese Medical College Guideline). Excluded control measures include Chinese medicine as a control. 4. Outcomes: Clinical efficacy, TCM syndrome score, survival rate. 5. Study design: Randomized controlled trials.

Information sources: We searched Englishand Chinese-language databases and followed the methods outlined in the Cochrane Handbook of Systematic Reviews. English-language databases included PubMed, Excerpta Medica Database (Embase), Cochrane Central Register of Controlled Trials (CENTRAL), including the Cochrane Library, and Allied and Complementary Medicine Database (AMED); Chinese-language databases included China SinoMed, China National Knowledge Infrastructure (CNKI), Chongqing VIP (CQVIP), and Wanfang Databases were searched from inception to SeptemberMarch 2021. No restrictions were applied.

Main outcome(s): Clinical efficacy, TCM syndrome score, survival rate.

Quality assessment / Risk of bias analysis: Risk of bias was assessed using the Cochrane Collaboration's procedures. R e v Man software (Version 5.2.3, Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2012) was used for risk of bias analysis. Items of bias assessed included sequence generation, allocation concealment, blinding of participants, blinding of personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting and other bias including baseline imbalance and funding. Risk of bias assessment was conducted by two independent reviewers and disagreement was resolved by discussion or consultation with a third person.

Strategy of data synthesis: We will use Endnote X8 (Thomson Reuters, USA) to manage our citations, and Review Manager Version 5.2.3 and stata 14.0 software will be used to create forest plots and conduct subgroup analysis and sensitivity analysis. For the binary variable, the effect size will be represented with risk ratio (RR) and 95% confidence interval (CI) and a mantel haenszel (M-H) method will be used to calculate them. For continuous variable, the effect size can be represented as mean difference (MD) and 95% CI. If one study reports its standard error (SEM) other than Standard Deviation (SD), we will convert SEM into SD. The heterogeneity of data will be investigated by Cochrane χ^2 and I^2 tests. The statistical heterogeneity will be considered substantial when $P < 0.05$ and $I^2>50\%$. If $P > 0.05$ and $I^2<50\%$, then the studies included are homogeneous and the differences between them can be ignored. If there is significant heterogeneity, the

random effects model will be used to pool data, and if there is no significant heterogeneity, then the fixed effect model will be used.

Subgroup analysis: Subgroup analysis were performed where possible, including studies with low risk for sequence generation, FBG level at baseline, patient age groups, disease duration, treatment duration, comparator drugs class.

Sensitivity analysis: Sensitivity analysis will be conducted to evaluate the stability of the results by excluding the studies one by one and then reanalyze the remaining studies in stata 14.0 software. If there are more than 10 studies included, then publication bias will be assessed by conducting funnel plot analysis and Egger s test. Finally, we will use the GRADE tool to evaluate the quality of evidence.

Country(ies) involved: China.

Keywords: Baitouweng decoction; radiation proctitis; efficacy; safety; systematic review; Network Pharmacology-Based Identification.

Contributions of each author:

Author 1 - Zihong Wu - The author designed the study and wrote the original draft.
Email: zihongwu90@126.com
Author 2 - Bei Yin - The author provided statistical expertise.
Author 3 - Zhixiang Yang - The author read, provided feedback and approved the final manuscript.