INPLASY PROTOCOL

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Conflicts of interest:
Authors have no conflict of interest to declare.

Efficacy and safety of Buzhong-Yiqi Decoction for Myasthenia gravis: study protocol for a systematic review

Huang, CH[1]; Xie, RF[2]; Liu, LT[3]; Wang, RQ[4].

Review question / Objective: **To evaluate whether Buzhong-Yiqi Decoction is effective in treating Myasthenia gravis.**
Condition being studied: **Buzhong-Yiqi Decoction, Myasthenia gravis.**
Information sources: **The following Electronic databases will be searched from their inceptions: PubMed, the Cochrane Library, Embase, the China National Knowledge Infrastructure (CNKI), Wanfang Database, Chinese Science and Technology Periodical Database (VIP), and Chinese Biomedical Literature Database (CBM). Search terms consist of disease (Myasthenia gravis, Lou Gehrig's disease) and intervention (Buzhong-Yiqi Decoction,Buzhong-Yiqi Tang). We'll also check the reference lists of eligible articles obtained from additional studies.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 May 2020 and was last updated on 22 May 2020 (registration number INPLASY202050080).

INTRODUCTION

Review question / Objective: **To evaluate whether Buzhong-Yiqi Decoction is effective in treating Myasthenia gravis.**

Condition being studied: **Buzhong-Yiqi Decoction, Myasthenia gravis.**

METHODS

Participant or population: **Participants with Myasthenia gravis must be diagnosed with a standard diagnostic criteria. There are no limitations on research subjects' age, gender, race, condition duration or intensity.**

Intervention: The experimental group only use Buzhong-Yiqi Decoction,Patients who received Buzhong-Yiqi decoction combined with other treatment measures will not be selected.

Comparator: The control group use western medicine.

Study designs to be included: Only Randomized controlled trials (RCTs) will be included.

Eligibility criteria: Only Randomized controlled trials (RCTs) will be included.

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Main outcome(s): Percentage of Clinical Effectiveness, Adverse events.

Additional outcome(s): Recurrence rate,Crisis incidence, clinical relative score, Acetylcholine receptor antibody (AChR-Ab) level.

Quality assessment / Risk of bias analysis: Two reviewers independently evaluated the methodological quality of included trials using the Cochrane risk of bias assessment tool. This tool has 7 domains, For each item, ROB was graded as high, low, or unclear. If the evaluation results were inconsistent, issues were resolved by rechecking the source papers and further discussions with the third reviewer.

Strategy of data synthesis: In this study, RevMan 5.3 software will be used for the meta-analysis. Dichotomous outcomes was performed using risk ratios (RRs)and 95% confidence intervals (95% CI) , continuous outcomes will be presented as weight mean differences (WMDs) . χ^2 test and Higgins I^2 test was used to test the heterogeneity. When P> 0.1 and I2 <50%, the fixed-effect model was used. On the contrary, the random-effect model was used. If the heterogeneity is obvious, try to find the source of heterogeneity, perform subgroup analysis. if the source of heterogeneity cannot be determined, descriptive analysis is performed. Potential publication bias was completed by Egger test conducted by stata14.0 software.

Subgroup analysis: If necessary, a subgroup analysis will be performed according to the type of western medicine in the control group such as Pyridostigmine Bromide, prednisone.

Sensibility analysis: The credibility of Meta analysis results is determined by sensitivity analysis according to methodological quality, sample size, and missing data.

Language: English.

Country(ies) involved: China.

Keywords: Buzhong Yiqi Decoction, Myasthenia gravis, protocol, systematic review.

Contributions of each author:
Author 1 - Chunhua Huang - Author 1 drafted the manuscript.
Author 2 - Rongfang Xie - The author provided statistical expertise.
Author 3 - Liting Liu - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 4 - Ruiqi Wang - The author read, provided feedback and approved the final manuscript.