# INPLASY PROTOCOL

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**Support:** **None.**

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

**Conflicts of interest:**
**None declared.**

# Reinforcing spleen and kidney method of Traditional Chinese Medicine for myasthenia gravis: a protocol for systematic review and meta-analysis

Peng, YX[1]; Li, L[2]; Pan, YT[3]; Ye, Q[4]; Chen, WY[5]; He, M[6]; Yang, XP[7]; Lu, BB[8].

**Review question / Objective:** **To evaluate the efficacy and safety of reinforcing spleen and kidney method of Traditional Chinese Medicine myasthenia gravis.**
**Information sources:** **A systematic literature search of articles published up to November 30th, 2021 will be conducted with the assistance of an experienced librarian in electronic databases: PubMed, Cochrane Library, EMBASE, Web of Science, China National Knowledge Infrastructure (CNKI),Wan fang, VIP Chinese Science and Technique Journals Database, the Chinese Bio Medical Database (CBM).Collect all the RCT on the treatment of with reinforcing spleen and kidney method of TCM in combination with or without any western medicine for the treatment of Myasthenia Gravis . While only English and Chinese will be applied in the study. Unpublished studies will not besought.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 December 2021 and was last updated on 02 December 2021 (registration number INPLASY2021120011).

## INTRODUCTION

**Review question / Objective:** **To evaluate the efficacy and safety of reinforcing spleen and kidney method of Traditional Chinese Medicine myasthenia gravis.**

**Condition being studied:** **We have the human, financial and material support for literature research. Our team has one doctor and several postgraduate students of TCM and Western medicine, and provides Chinese and English database for paper writing and literature search.**

## METHODS

**Participant or population:** We will include patients with myasthenia gravis (according to any recognized diagnostic criteria, such as The Chinese Expert Consensus on The Diagnosis and Treatment of Myasthenia Gravis or the diagnosis criteria set by the Myasthenia Gravis Foundation of America (MGFA)). There are no limitations on research subjects' age, gender, race, condition duration or intensity. And we will exclude patients with severe cardiovascular diseases, mental illnesses, etc.

**Intervention:** The intervention measures of the experimental group were using the types of reinforcing spleen and kidney method of Traditional Chinese medicine for oral administration (such as Chinese herbal medicine, Chinese patent medicine) combined with or without western conventional medicine. While research subjects who received other treatment measures of Traditional Chinese medicine will not be selected.

**Comparator:** The control group used one or more western conventional medicine (such as: Acetylcholine preparation, hormone, immunosuppressant, intravenous immunoglobulin, etc.), placebo control, no therapy. There are no limitations on intervention approaches.

**Study designs to be included:** Randomized clinical trial (RCT) with no limitation of blinding will be included. The animal mechanism studies, case reports, self-pre- and post-control, or non-RCTs will be excluded.Eligibility criteria: Only Randomized controlled trials (RCTs) will be included.

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**Main outcome(s):** a) Clinical absolute score, and relative score. b) The Quantitative Myasthenia Gravis (QMG) scores, clinical absolute score, and clinical relative score. c)Effective rate, which includes cured, marked improvement, improvement. d) Serological test indicators: such as acetylcholine receptor antibody (AChR-Ab), interleukin-6(IL-6), interleukin-4(IL-4), IFN-α, IFN-γ, Musk-ab, CD3+, CD4+, CD8+, CD4+/ CD8+,IgM, IgA, IgG, etc.

**Additional outcome(s):** a) Life quality score, such as activity daily living (ADL), the MOS 36-Item Short Form Health Survey (SF-36), Myasthenia Gravis Quality of Life SCALE (MG-QOL 15), Busch Quality of live evaluation ,etc. b) Adverse events. c) Indicators of Electromyography. d) Traditional Chinese medicine syndrome score e) The recurrence rate.

**Data management:** Two researchers will independently browse the selected articles and extra the efficiently articles. Writing down the reason of eliminated Articles, and any disagreement will be solved by discussing with the third researcher. The selected data from these articles included as follows: 1.Essential information: the first author, the year of publication, and country; 2.Study design: setting, inclusion and exclusion criteria, randomization method, blinding, sample size, drop outs; 3.Participants: gender, age, and disease duration; 4.Methodological characteristics: title study design, MG severity, and diagnostic criteria; 5.Details of intervention: type of intervention, duration of treatment, and follow-up time; 6.Outcome measures.

**Quality assessment / Risk of bias analysis:** The methodological quality of randomized controlled trials will be assessed with the Cochrane Collaboration's risk of bias tool. This tool will pay attention to the following domains: generation of random sequence, allocation concealment, blinding of participants and personnel, incomplete outcome data, duration of follow-up, selective reporting, and other bias. Any disagreements between the reviewers will be solved through discussion or seeking advice from the third reviewer.

**Strategy of data synthesis:** When meta-analysis is possible, the date synthesis will be represented with RevMan V.5.3 statistical software. The statistically data is meaningful on the $p<0.05$ basis, We will use the SMD with 95% CIs to evaluate continuous outcomes, and the RR with 95% CIs to evaluate dichotomous data. The fixed effects model ($I^2 < 50\%$)will be used to estimate the RR and MD ,or the random effects model ($I^2 > 50\%$) will be considered to the indicative of substantial statistical heterogeneity, while used for the synthesis the data and subgroup analysis or sensitivity analysis. The funnel plots will be indicated for the obvious publication bias.

**Subgroup analysis:** If necessary, a subgroup analysis will be performed.

**Sensitivity analysis:** We will conduct the sensitivity analysis to evaluate the robustness and reliability of the pooled results. Meanwhile, if there are adequate data available to analyze, we will conduct a sensitivity analysis on the primary outcomes to test the strength of the review conclusions, including the quality of the methods and studies, and the impact of sample size and missing data.

**Language:** English or Chinese.

**Country(ies) involved:** China.

**Keywords:** reinforcing spleen and kidney, Traditional Chinese Medicine, myasthenia gravis, systematic review.

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