

INPLASY PROTOCOL

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None declared.

Tonifying Spleen and Replenishing Kidney method of Traditional Chinese Medicine for myasthenia gravis: a protocol for systematic review and meta-analysis

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Review question / Objective: To evaluate the efficacy and safety of Tonifying Spleen and Replenishing Kidney method of Traditional Chinese Medicine for myasthenia gravis.

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

Information sources: The following Electronic databases will be searched from their inception: PubMed, Cochrane Library, EMBASE, Web of Science, Springer, China National Knowledge Infrastructure (CNKI), Wan fang, VIP Chinese Science and Technique Journals Database, the Chinese Bio Medical Database (CBM). We'll also check the reference lists of eligible articles obtained from additional studies. The retrieval time is from the inception of the database to March 31, 2021. The language is limited to Chinese and English, while unpublished studies will not be sought. Searches will be re-run prior to the final analysis.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 January 2021 and was last updated on 26 January 2021 (registration number INPLASY202110097).

INTRODUCTION

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METHODS

Participant or population: We will include patients with myasthenia gravis(according to any recognised diagnostic criteria, such as The Chinese Expert Consensus on The Diagnosis and Treatment of Myasthenia Gravis or the diagnosis criteria setted by the Myasthenia Gravis Foundation of America(MGFA)).The patient should be approximately 18 years old. Not restricted in gender, ethnicity, race and disease stage. 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 tonifying spleen and replenishing 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 patients who received other treatment measures of Traditional Chinese medicine will not be selected.

Comparator: The control group use one or more western 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: Only the study of Randomized controlled trials(RCTs) will be included by us.The animal mechanism studies, case reports, self-pre- and post-control, or non-RCTs will be excluded.

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Main outcome(s): 1)Effective rate. 2)The Quantitative Myasthenia Gravis (QMG) scores. 3)Adverse events. 4)The Quality of life QOL(include:Medical Outcome Survey 36-item Short Form Health Survey, SF-36. Or 15-item Myasthenia Gravis Quality-of-Life Scale, MGQOL-15 ,etc.).

Additional outcome(s): 1)AchRAB: The concentration of acetylcholine receptor antibody(AchRAB) in Serum. 2)Serum related immune cells: The change of related immune cells in serum, such as CD3+CD4+cell,CD4+/CD8+cell. 3) Traditional Chinese Medicine Syndrome Score Scale(TCMSSS). 4)The serum Interleukin 6 level. 5)The level of IFN- γ and it's mRNA. 6)Clinical score calculated based on The Chinese Expert Consensus on The Diagnosis and Treatment of Myasthenia Gravis. The clinical score contains the Clinical Absolute Score (CAS) and Clinical Relative Score(CRS).

Data management: The EndNote X9 document management software and Microsoft Excel will be used to extract data. The two researchers will independently extract the following data: author, title, year of publication, interventions of experimental groups and control groups, sample size, interventions, study methods, primary and secondary outcome measures, and any adverse events, etc. The disagreements related to

data extraction will be resolved by reaching a consensus or consulting the third author.

Quality assessment / Risk of bias analysis:

The Cochrane Collaboration's risk of bias tool will be applied to assess the methodological quality of randomized controlled trials. This tool will be worked on 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. The discussion of two reviewers will clear away the any disagreements, If there are still inconsistencies, we will be consult advice from the third reviewer.

Strategy of data synthesis: If meta-analysis is possible, RevMan V.5.3 statistical software will be applied to the data synthesis. P values <0.05 will be deemed to the statistically significant. the the SMD with 95% CIs will be used for evaluating continuous outcomes, and while the RR with 95% CIs will be employed to evaluate dichotomous data. we will have use of the fixed effects model ($I^2 < 50\%$) to estimate the RR and MD, or the random effects model ($I^2 > 50\%$) to indicate substantial statistical heterogeneity, while use for the synthesis the data and subgroup analysis or sensitivity analysis. The funnel plots will be showed for the obvious publication bias.

Subgroup analysis: If necessary, a subgroup analysis will be performed according to the type of myasthenia gravis with general myasthenia gravis and ocular myasthenia gravis.

Sensitivity analysis: To evaluate the reliability of our study results, we will conduct a sensitivity analysis of the included literature and will eliminate low-quality literature.

Language: English.

Country(ies) involved: China.

Keywords: Tonifying Spleen and Replenishing Kidney method of Traditional

Chinese Medicine, Myasthenia gravis, protocol, systematic review.

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