INPLASY PROTOCOL

Corresponding author:
Yuxuan Peng

773613431@qq.com

Author Affiliation:
Chengdu 8th People's Hospital (Chengdu Chronic Diseases Hospital, Chengdu Elderly Services Demonstration Training Center)

Support: None.

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

Conflicts of interest: None.

External treatment of Traditional Chinese Medicine for myasthenia gravis: a protocol for systematic review and meta-analysis

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

Review question / Objective: To evaluate the efficacy and safety of external treatment of Traditional Chinese Medicine for myasthenia gravis.

Condition being studied: Myasthenia gravis. 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: A systematic literature search of articles published up to February 28th, 2021 will be conducted with the assistance of an experienced librarian in electronic databases: 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).Collect all the RCT on the treatment of with external treatment 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 Unpublished studies will not be sought.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 January 2021 and was last updated on 21 January 2021 (registration number INPLASY202110083).

INTRODUCTION

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Condition being studied: Myasthenia gravis. 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

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METHODS

Search strategy: A systematic literature search of articles published up to February 28th,2021 will be conducted with the assistance of an experienced librarian in electronic databases: 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).

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 Graxis 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: We will include one or more external treatment of TCM(such as: acupuncture, electroacupuncture, transcutaneous electrical nerve stimulation, acupoint catgut embedding, moxibustion, warm acupuncture, acupressure, cupping jar, fire needle, auricular acupuncture, scalp needle, abdominal acupuncture, superficial acupuncture bleeding, acupoint injection, needle knife, point application, Tuina, Traditional Chinese medicine fumigation and washing) in combination with or without any western medicine for the treatment of Myasthenia Gravis.

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: 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.

Information sources: A systematic literature search of articles published up to February 28th,2021 will be conducted with the assistance of an experienced librarian in electronic databases: 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).Collect all the RCT on the treatment of with external treatment 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 be sought.

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: 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: A subgroup analysis will be performed according to control intervention and different outcomes to explore the causes of heterogeneity including clinical or methodological reasons.

Sensibility 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.

Country(ies) involved: China.

Keywords: external treatment of Traditional Chinese Medicine, Myasthenia gravis, protocol, systematic review.

Contributions of each author:
Author 1 - Yuxuan Peng.
Email: DRxuan2020@163.com
Author 2 - Lu Li.
Email: aluluya1996@163.com
Author 3 - Yuting Pan.
Email: yuting199031@163.com
Author 4 - Bibo Lu.
Email: mxblbb2020@163.com
Author 5 - Qing Ye.
Email: ye511416@163.com
Author 6 - Min He.
Email: xialuoshang@sina.com
Author 7 - Weiyin Chen.
Email: chenwydoctor@sina.com
Author 8 - Xueping Yang.
Email: 13408419010m0@sina.cn