

INPLASY PROTOCOL

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**Review Stage at time of this
submission:** The review has
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Conflicts of interest:

None declared.

Electroacupuncture therapy for ophthalmoplegia Protocol for a systematic review

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Review question / Objective: Our systematic review will provide evidence to determine whether electroacupuncture is an effective and safe intervention for ophthalmoplegia patients.

Condition being studied: Acupuncture has been widely used to treat ot of nervous system diseases, such as stroke, vascular dementia, and facial paralysis, especially ophthalmoplegia in China.

Information sources: We will retrieve the literature from the following electronic databases, by December 31, 2021, such as PubMed, EMBASE, the Cochrane Library, Web of Science database, Chinese BioMedical Literature Database, China National Knowledge Infrastructure, China Science and Technology Journal database, and Wanfang Database.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 February 2022 and was last updated on 09 February 2022 (registration number INPLASY202220023).

INTRODUCTION

Review question / Objective: Our systematic review will provide evidence to determine whether electroacupuncture is an effective and safe intervention for ophthalmoplegia patients.

Rationale: According to traditional Chinese Medicine (TCM) theory, acupuncture is a type of treatment, which stimulates acupoints by inserting a filiform needle to

regulate the balance of Qi and blood. Many clinical trials indicate that electroacupuncture may promote the recovery of extraocular muscles in ophthalmoplegia patients. We aim to conduct a meta-analysis to evaluate the efficacy and safety of electroacupuncture for ophthalmoplegia.

Condition being studied: Acupuncture has been widely used to treat ot of nervous system diseases, such as stroke, vascular

dementia, and facial paralysis, especially ophthalmoplegia in China.

METHODS

Search strategy: acupuncture, acupuncture therapy, acupoints, manual acupuncture, body acupuncture, electro-acupuncture, electroacupuncture, auricular acupuncture, scalp acupuncture, ocular acupuncture, fire needling, warm needling, plum blossom needle, ophthalmoplegia, ophthalmoparesis, oculomotor paralysis, abducens paralysis, trochlear palsy, external ophthalmoplegia, and diplopia.

Participant or population: People with a diagnosis of ophthalmoplegia will participate without considering any information related to their age, sex, race, education, nationality, or economic status.

Intervention: In the experimental groups, we plan to include the following acupuncture therapies: manual acupuncture, body acupuncture, electroacupuncture, dermal needle, scalp acupuncture, ocular acupuncture. Pharmacopuncture, acupoint injection, laser acupuncture, moxibustion, cupping, and transcutaneous electrical nerve stimulation will be excluded. In addition, there is limitation to the test cycle and treatment frequency.

Comparator: In the control groups, we plan to use the categories: no treatment, sham acupuncture, placebo acupuncture, and drug therapy. We will include studies that have compared electroacupuncture plus another therapy with the same other therapy alone. We will also exclude RCT which have compared 2 different types of acupuncture or compared acupuncture with TCM, moxibustion, and other TCM treatment.

Study designs to be included: According to the inclusion, a standard data collection form will be made before data extraction. Two reviewers will independently extract data from the selected studies and fill in the data collection form. The discrepancies and uncertainties will be resolved to get a

consensus by consulting a senior reviewer through discussion. We will contact the corresponding authors for more information if the details of the trials were not completed. All data will be cross-checked and transferred into review manager software.

Eligibility criteria: 1. Types of studies. This review will include clinical RCTs of electroacupuncture therapy for ophthalmoplegia without any language or publication status restrictions. Non-RCTs, quasi RCTs, case series, case reports, crossover studies, uncontrolled trials, and laboratory studies will not be included. 2. Types of participants. People with a diagnosis of ophthalmoplegia will participate without considering any information related to their age, sex, race, education, nationality, or economic status. 3. Types of interventions 3.1. Experimental interventions. In the experimental groups, we plan to include the following acupuncture therapies: manual acupuncture, body acupuncture, electroacupuncture, dermal needle, scalp acupuncture, ocular acupuncture. Pharmacopuncture, acupoint injection, laser acupuncture, moxibustion, cupping, and transcutaneous electrical nerve stimulation will be excluded. In addition, there is limitation to the test cycle and treatment frequency.

Information sources: We will retrieve the literature from the following electronic databases, by December 31, 2021, such as PubMed, EMBASE, the Cochrane Library, Web of Science database, Chinese BioMedical Literature Database, China National Knowledge Infrastructure, China Science and Technology Journal database, and Wanfang Database.

Main outcome(s): The primary outcome measurement will be an improvement of eyeball moving distance, size of fissure palpebrae, and the reduced degree of strabismus. The eyeball moving distance and size of fissure palpebrae will be measured by a ruler. The ruler unit is accurate to the millimeter. The reduced

degree of strabismus is evaluated by a validated scale, such as Strabismus scale.

Additional outcome(s): Size of the pupil. 2. Main symptom scores before and after treatment. 3. Ocular localization analysis and functional impairment extent. 4. Safety: measured by incidence and severity of side effects. Size of the pupil. 2. Main symptom scores before and after treatment. 3. Ocular localization analysis and functional impairment extent. 4. Safety: measured by incidence and severity.

Quality assessment / Risk of bias analysis: The risk and bias in included studies will be assessed independently by 2 reviewers using the risk of bias (ROB) assessment tool in the Cochrane Handbook. The following domains will be assessed: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other bias. We will give each index a low bias, unclear, or high bias, and any discrepancies will be resolved by a discussion between the 2 reviewers or consulting a third reviewer.

Strategy of data synthesis: We will use Review Manager software (RevMan V.5.3.5) provided by Cochrane Collaboration for data synthesis and analysis. When $I^2 < 50\%$, a fixed-effects model will be used to calculate the RR and MD. When $I^2 \geq 50\%$, we will use a random-effects model to synthesize the data. Subgroup analysis will be performed and the potential reasons will be analyzed to explore the causes of heterogeneity. If meta-analysis is not appropriate, we may use narrative synthesis.

Subgroup analysis: If we identify substantial heterogeneity, we will perform subgroup analysis for different intervention forms. We will take acupuncture therapy types, the degree of ophthalmoplegia severity, the age of patients, and other different control interventions into consideration.

Sensitivity analysis: We will perform sensitivity analysis for primary outcomes to test the robustness of the review conclusions, and we will still evaluate the impact of methodological quality, sample size, and missing data.

Country(ies) involved: China.

Keywords: electroacupuncture; acupuncture; ophthalmoplegia; protocol; systematic review.

Contributions of each author:

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