INPLASY PROTOCOL

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

Conflicts of interest:
None declared.

Effectiveness and safety of electroacupuncture therapy for ophthalmoplegia: A protocol for systematic review and meta-analysis

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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 10 March 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: (1) Electronic searches.We will collect relevant articles by searching the following databases: 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. According to the Cochrane Handbook Guidelines, all reviewers will discuss the search terms and search strategies. All databases will be searched from creating to December 31, 2021, by the following words: acupuncture, electroacupuncture, ophthalmoplegia, ophthalmoparesis, oculomotor paralysis, abducens paralysis, trochlear palsy, external ophthalmoplegia, diplopia, RCT, etc.The equivalent search terms will be translated into Chinese while searching in the Chinese databases. The search strategy for PubMed is shown in Table 1.(2) Searching other resources. We will search the reference list of the included studies and existing systematic reviews related to our topic. We will also search for other literature resources, including the Chinese Clinical Trial Register, conference papers, and other related gay literature to make our search as complete as possible.

Participant or population: All patients should be diagnosed with ophthalmoplegia and should be older than 18 years of age. However, race, gender, and educational status are not limited.

Intervention: The methods of electroacupuncture include Filifrom-Needle electrocupuncture, Fire-Needle electrocupuncture, Scalp electro-cupuncture Abdominal electrocupuncture, and Electroelectrocupuncture. Pharmacoacupuncture, acupoint injection, laser acupuncture, moxibustion, cupping, transcutaneous electrical nerve stimulation will be excluded. If there are other adjuvant therapies, the two groups should be consistent.

Comparator: In the control groups, we plan to use the categories: no treatment, sham acupuncture, placebo acupuncture, and drug therapy. Wewill 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: Two researchers independently screened the literature according to eligibility criteria. First, duplicate articles were eliminated using EndNote V.x 9.0, and excluded articles that did not meet the inclusion criteria by reading the title and subject. Second, they will perform a screen again of the remaining articles by reading the full text according to the inclusion and exclusion criteria and determine whether it is available for the systematic review. We will also record the excluded papers and explain the reasons for this; the specific screening process is shown in figure 1. If there is disagreement during, the third researcher will be invited to make a decision.

Eligibility criteria: We will include only randomized controlled clinical trials (RCTs) of electroacupuncture therapy for ophthalmoplegia.We will exclude any other literature including non-randomized clinical controlled trials, retrospective research literature, conference abstracts, case reports, repeated published literature, and literature of information without data.

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 main outcome will be an improvement of eyeball moving distance, size of fissure palpebrae, and the reduced degree of strabismus.

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.

Dara management: Data extraction will be performed independently by two reviewers (who and who), and the results will be cross-matched. When the differences and opinions are inconsistent, they should be settled through discussion. If the differences encountered cannot be resolved through discussion, a third researcher will be invited to resolve them. Excel will be used to extract data, including the first author, country, year of publication, patient characteristics, number of participants, interventions, outcomes, results, main conclusions, conflicts of interest, ethical approval, and other information. If necessary, we will contact the corresponding author by e-mail to obtain more accurate data.

Quality assessment / Risk of bias analysis: We used complete case data as the analysis data. Heterogeneity will be assessed using a standard x2 test with a significance level of P<0.1 and I2test. When the I2 value was <50%, the study was considered to have no statistical heterogeneity and the fixed-effect model was selected. Although I2 ≥50%, the study will be considered to have substantial heterogeneity, and we will select a random effects model. 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 V.5.1.0.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, unclear, or high bias, and any discrepancies will be resolved by a discussion between the two reviewers or by consulting a third reviewer.

Strategy of data synthesis: We will use the Review Manager software (RevMan 5.4.1) provided by the Cochrane Collaboration for data synthesis and analysis. When I2<50%, a fixed-effects model was used to calculate the RR and MD. When I2 ≥50%, we used a random-effects model to synthesize the data. A subgroup analysis will be performed, and the potential reasons will be analyzed to explore the causes of heterogeneity. If a meta-analysis is inappropriate, narrative synthesis may be used.

Subgroup analysis: If we identify substantial heterogeneity, we will perform subgroup analysis for different intervention forms. We will consider acupuncture therapy types, degree of ophthalmoplegia severity, patient age, sex, race, course, sample size, different methods of electroacupuncture, and other possible factors affecting the results.

Sensitivity analysis: To test the stability and reliability of the results of this study, we conducted a sensitivity analysis according to the following points: method quality, sample size, and missing data. After that, we will perform a data analysis again and compare the results. If there was no directional change after the sensitivity analysis, the results were stable.

Country(ies) involved: China.

Keywords: Acupuncture, electroacupuncture, ophthalmoplegia, protocol, systematic review.

Dissemination plans: Ethical approval was not required because no primary information of individual patients was collected. We will publish this article in a peer-reviewed journal.

Contributions of each author:

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