INPLASY PROTOCOL

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Review Stage at time of this submission: Preliminary searches.

Conflicts of interest: None declared.

Effectiveness and safety of acupuncture in the treatment of oculomotor nerve palsy：A protocol for systematic review and meta analysis

Yang, Y[1]; He, X[2]; Kong, D[3]; Wang, C[4]; Mu, Y[5]; Zhang, Y[6]; Hu, S[7].

Review question / Objective: This study will conduct an evaluation about the efficacy of acupuncture for oculomotor nerve palsy, making up for the lack of relevant clinical evidence.

Condition being studied: The oculomotor nerve is the third pair of cranial nerves in the human body, which together with the trochlear nerve and the abducens nerve innervate the eye movement. The etiology of ophthalmoplegia is various, which is one of the more common eye diseases in clinic.Western medicine for the early treatment of this disease there is no special treatment, more hormones, vitamins, energy mixture, vasodilators and other treatment.In recent years, with the development of traditional Chinese medicine, acupuncture as the main method of traditional Chinese medicine therapy in the clinical treatment of oculomotor nerve palsy has been gradually promoted, the efficacy is mixed. So, this study will conduct an evaluation about the efficacy of acupuncture for oculomotor nerve palsy, making up for the lack of relevant clinical evidence.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 April 2021 and was last updated on 31 May 2021 (registration number INPLASY202140074).

INTRODUCTION

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METHODS

Participant or population: All patients diagnosed with ONP were included, and there were no limitations on gender, age, or race.

Intervention: All types of acupuncture treatment will be included, such as body acupuncture, electro-acupuncture, auricular acupuncture, warm acupuncture, fire needling, elongated needle and moxibustion. Neither the number of treatments nor the length of treatment will be restricted in this review.

Comparator: Control interventions may include one of the following treatment methods: general care, sham acupuncture, placebo, physical/mental training therapy, adjuvant chemotherapy or other pharmacotherapy.

Study designs to be included: In addition to individual case reports, review, the summaries of experience, animal studies, and non-randomized controlled trials (RCTs), this study will include all RCTs of acupuncture therapy in patients with ONP, regardless of language or publication status.

Eligibility criteria: This study will include all RCTs of acupuncture therapy in patients with ONP, regardless of language or publication status.

Information sources: The scope of search includes the Medline, Embase, Cochrane Central Register of Controlled Trials (CENTRAL), China National Knowledge Infrastructure (CNKI), Wanfang Database, Chinese Biomedical Literature Database (CBM), and Chinese Scientific Journal Database (VIP database), and other databases, with the deadline of On April 12, 2021.

Main outcome(s): Primary outcome · Palpebral fissure size · Diplopia grade rating table · Angle of eye strabismus or degree of eye movement Secondary outcomes Quality of life assessment scale (SF-36).

Quality assessment / Risk of bias analysis: In order to assess the quality of relevant trials, Two reviewers will apply the Cochrane Bias risk Assessment tool, respectively. The extracted details include the random sequence generation, the blindness of result evaluation, the blindness of participants and personnel, the concealment of allocation, the reporting of selective results, the incomplete result data, and so on. In the meantime, they are divided into 3 different levels: fuzzy, low, and high. When the relevant information to research project is found unavailable, contact will be made with the author of the project to obtain the required information. In case of any dispute, a more sensible decision will be made with the assistance of the Third investigator .

Strategy of data synthesis: RevMan5.3 software was applied to conduct data analysis. Relative risk was treated as the effect analysis statistic for binary variables. Mean difference was taken as the effect analysis system for continuous variables, and 95% confidence interval was adopted to carry out interval estimation. The heterogeneity between the results using Chi-square test analysis (alpha test level = 0.1), and combining with quantitative judgment I2 heterogeneity is big is small, if I2 ≤ 50%, P ≥ .1, show good homogeneity between the various research, using the fixed effects model, if not that the statistical heterogeneity between the results of the study is larger, should further analyze sources of heterogeneity, and use

the random effects model. If the level of clinical heterogeneity is significant, sensitivity analysis will be conducted, otherwise only descriptive analysis will be carried out.

Subgroup analysis: If there is substantial heterogeneity between the study results, subgroup analysis will be performed, following items will be considered: type of acupuncture, gender, age, and outcome styles.

Sensitivity analysis: When sufficient data are available, sensitivity analysis will be conducted to verify the robustness of the results. It includes the impact of methodological quality, study design and sample size.

Country(ies) involved: China.

Keywords: acupuncture, efficacy, safety, oculomotor nerve palsy, protocol, systematic review.

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