INPLASY PROTOCOL

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Conflicts of interest:
None declared.

The efficacy and safety of acupuncture for stroke patients with sleep apnea syndrome: A protocol for systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: **The purpose of this systematic review and meta-analysis of randomized controlled trials was to evaluate the efficacy and safety of acupuncture for stroke patients with sleep apnea syndrome.**
Condition being studied: **Sleep apnea syndrome (SAS) is a sleep disorder in which breathing stops during sleep, accompanied by snoring, morning headache, daytime lethargy, memory loss and other symptoms. Its diagnosis is mainly confirmed by polysomnography monitoring (PSG). According to the etiology, it can be divided into central type, blocking type and mixed type, with blocking type being the most common. It usually tends to occur in men, overweight middle-aged and elderly people, which is easy to combine with hypertension, coronary heart disease, stroke and other cardiovascular and cerebrovascular diseases. The prevalence of SAS after stroke is 50%-75%. SAS may precede or follow stroke, and may affect the outcome of rehabilitation weeks or months after stroke. As a risk factor for stroke, SAS can be treated, but there is no specific drug for this disease, while instruments, such as continuous positive airway pressure, CPAP), and surgical method are usually used for treatment. But the patient compliance is poor and the degree of acceptance is not high, so the treatment effect is affected. Acupuncture of SAS has the advantages of simple operation, considerable curative effect and less adverse reactions. However, there is still uncertainty about its safety and efficacy. Therefore, we plan to evaluate the efficacy and safety of acupuncture for the treatment of stroke patients with sleep apnea syndrome.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 May 2022 and was last updated on 17 May 2022 (registration number INPLASY202250113).

INTRODUCTION

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METHODS

Participant or population: Patients should be clearly diagnosed with stroke and sleep apnea syndrome. There was no restriction on the type of stroke or SAS, age, gender, race, education, socioeconomic status, etc.

Intervention: The intervention measures in the treatment group will be acupuncture used alone or acupuncture combination other therapies. There is no restriction on acupuncture point selection principles, techniques, needle specifications, electroacupuncture, etc.

Comparator: The control group received the usual treatment for stroke and other diseases of the patients, but did not include acupuncture.

Study designs to be included: Randomized controlled trials (RCTs).

Eligibility criteria: All studies were randomized controlled trials (RCTS), in Chinese or English, with or without assignment concealment and blinding. Animal studies, cohort studies, case-controlled studies, case reports and expert experience will be excluded.

Information sources: PubMed, the Cochrane Library (CENTRAL), Embase, Web of Science, China National Knowledge Infrastructure (CNKI), Chongqing VIP Information (VIP), and WanFang Data, China Biomedical Literature Database (CBM), ClinicalTrials.gov and Chinese Clinical Trial Registry (ChiCTR).

Main outcome(s): The primary outcome assessed will be the total effective rate and Apnea-hypopnea index (AHI).

Additional outcome(s): Secondary outcome measures include minimal oxygen saturation (SaO2min), longest apnea time, Epworth Sleepiness Scale (ESS), and adverse reaction, etc.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the quality of the selected studies according to the Cochrane Collaboration's tool for randomized control trials. Items will be evaluated in three categories: low risk of bias, unclear risk of bias and high risk of bias. The following seven characteristics will be assessed: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other biases. Results

from these questions will be graphed and assessed using Review Manager 5.4.

Strategy of data synthesis: The meta-analysis will be performed by the Review Manager 5.4 software. The dichotomous variables will be assessed by risk ratios (RR) with 95% confidence intervals (95% CIs) and continuous variables will be analyzed with their mean difference (MD) or standard mean difference (SMD) with 95% CIs. According to the results of the heterogeneity test, random effect model or fixed effect model will be selected for data analysis. Between-study heterogeneity will be assessed using x^2 test and I^2 statistic. If $I^2<50\%$ then the fixed-effect model will be applied for data synthesis. Otherwise, the random-effect model will be conducted if the heterogeneity is significant ($I^2\geq50\%$). Outcomes will be calculated using P values and $P<0.05$ is considered statistically significant.

Subgroup analysis: If the necessary data are available, subgroup analyses will be performed to investigate differences in gender, age, berberine dosage, etc.

Sensitivity analysis: Sensitivity analysis will be performed to assess the stability of the decision. It includes influences such as study quality, study design and sample size. In addition, we will present the results of sensitivity analysis in the summary table.

Country(ies) involved: China.

Keywords: Sleep Apnea Syndrome, Stroke, Systematic Review, Meta Analysis.

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