

# INPLASY PROTOCOL

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**Corresponding author:**  
Xiangzhe Liu

liuxiangzhe@163.com

**Author Affiliation:**  
Henan University of Chinese  
Medicine

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**Conflicts of interest:**  
The authors have no conflicts of interest to disclose.

## INTRODUCTION

**Review question / Objective:** With this systematic review and if possible meta-analysis we urge to further evaluate the effectiveness and safety of acupuncture for headache caused by CH. The results will offer clinical decisions for Neurologist.

## Acupuncture for headache caused by cerebral hemorrhage: A protocol for a systematic review and meta-analysis

Ran, C<sup>1</sup>; Liu, X<sup>2</sup>; Sun, J<sup>3</sup>; Zhang, Y<sup>4</sup>; Bai, C<sup>5</sup>; Li, M<sup>6</sup>.

**Review question / Objective:** With this systematic review and if possible meta-analysis we urge to further evaluate the effectiveness and safety of acupuncture for headache caused by CH. The results will offer clinical decisions for Neurologist. **Condition being studied:** Some headaches are secondary to cerebrovascular disorders .From literature, we are fully aware that in many cerebrovascular diseases, headache is the only symptom at onset or predominates over the other neurological features , Indeed, the third edition (beta version) of the International Classification of Headache Disorders (ICHD-3) d e d i c a t e s an entire chapter to headache attributed to cranial or cervical vascular disorder.For cerebral hemorrhage, headache is also one of the most common clinical symptoms.According to research, acupuncture can effectively relieve headaches. At present,however, no study has systematically evaluated the effectiveness and safety of acupuncture for the treatment of headache caused by CH with higher level evidence. Therefore, this systematic review aims to assess the effectiveness and safety of acupuncture for the treatment of headache following CH.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 June 2020 and was last updated on 01 June 2020 (registration number INPLASY202060002).

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## METHODS

**Participant or population:** Patients with headache following CH, regarding sex, age, and race will all be included. However, patients are diagnosed with headache before the CH, or result from other disorders, and Patients who have used antidepressants, topical anesthetics and other drugs to treat headache within 3 months will be excluded.

**Intervention:** The patients in the treatment group received acupuncture (no restriction on the methods of operation and course of treatment) and guideline-recommended conventional treatment.

**Comparator:** The control group could gain guideline-recommended conventional treatment and a placebo or no treatment or exercise.

**Study designs to be included:** All the RCTs of acupuncture for headache caused by CH patients will be included without publication status restriction or writing language.

**Eligibility criteria:** All the RCTs of acupuncture for headache caused by CH patients will be included without publication status restriction or writing language. Letters to editors, review articles, case reports, conference abstracts, cross-sectional studies, and all observational studies will be excluded. Patients with headache following CH, regarding sex, age, and race will all be included. However,

patients are diagnosed with headache before the CH, or result from other disorders, and Patients who have used antidepressants, topical anesthetics and other drugs to treat headache within 3 months will be excluded.

**Information sources:** Electronic databases including English databases (PubMed, MEDLINE, EMBASE, Web of Science, Cochrane Library) and Chinese databases (China National Knowledge Infrastructure, China Biology Medicine Database, Wanfang Database, VIP Database) will be searched from their inception to May 2020 with no language restrictions to recognize related studies. The RCTs that evaluate the effectiveness and safety of acupuncture for headache caused by CH will be included. Besides, the reference lists of review articles will be searched for any possible titles matching the inclusion criteria. Similar strategies will be applied to the other electronic databases in this study. The researchers will also scan the database of Henan University of Traditional Chinese Medicine Library and consult the experts in Neurology. Dissertations of degrees will be included. The WHO International Clinical Trials Registry Platform and Google Scholar will be scrutinized for potential results. Also, the Clinical Trials govregistry will be explored for any unpublished trials.

**Main outcome(s):** The primary outcome includes headache, as measured by the NRS of Pain assessment scale, or other associated scales.

**Additional outcome(s):** The secondary outcomes include disturbance of consciousness, as assessed by the MoCA Scale or other related score tools; dizziness, as evaluated by DHI, or other relevant scales; and quality of life, as examined by activities of daily living scale or any other specific scales. In addition, adverse events are also assessed.

**Data management:** Upon completion of the retrieval, the two reviewers will independently read and extract the data

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from the study. Data will include the following information: title, abstract, first author and corresponding author, the country, the publication time, publications, participants, demographic characteristics (age, baby and family situation, regional, ethnic, and national), the number of participants, diagnostic criteria, types, intervention, intervention characteristics, the results of the study, the incidence of adverse events and type. We will use a standardized data extraction table to extract the above data. Any disagreement between the two reviewers will be decided by consensus or with the participation of a third reviewer.

#### **Quality assessment / Risk of bias analysis:**

The risk of bias will be independently assessed by two reviewers and any differences will be resolved through consultation or the participation of a third reviewer. The RCTs will be evaluated using the Cochrane "risk of bias assessment" tool. The tool assesses the risk of bias mainly in the following 7 aspects: random sequence generation, allocation concealment, the blinding method for patients, researchers and outcomes assessors, incomplete result data, and selective reports. As recommended by the Cochrane manual, the risk of bias in each of these areas will be assessed as low or high depending on whether the criteria were met or not met, and the lack of information will be recorded as unclear. In most cases, disagreements will be settled by discussion between the 2 reviewers. If disagreement remained after discussion, a third reviewer will be consulted before taking the final decision on the disagreements.

**Strategy of data synthesis:** We will use RevMan 5.3 software to carry out the data synthesis and meta-analysis. If heterogeneity is acceptable ( $I^2 < 50\%$ ), a fixed-effect model will be utilized to synthesize the data, and meta-analysis will be performed. On the other hand, if heterogeneity is significant ( $I^2 > 50\%$ ), a random-effect model will be used to pool the data and to operate the meta-analysis. In such a situation, subgroup analysis will

be conducted to identify the factors that may cause the significant heterogeneity. If there is still substantial heterogeneity after the subgroup analysis, then data will not be pooled, and meta-analysis will not be conducted. Instead, a narrative summary will be described.

**Subgroup analysis:** If there is a significant heterogeneity in the included trials, subgroup analysis based on treatment, Painful area, Pain level, and other potential factors will be performed to explore the possible factors of heterogeneity.

**Sensibility analysis:** A sensitivity analysis will be performed to test the robustness of the review result and to detect the source of heterogeneity. This can be done by excluding trials with a high risk of bias or eliminating each study individually. And, the impact of methodological quality, sample size, and missing data will be assessed. Then the analysis will be repeated after the exclusion of low methodological quality studies and the results compared with the previous meta-analysis.

**Country(ies) involved:** China.

**Keywords:** acupuncture, cerebral hemorrhage, headache, effectiveness, safety, systematic review.

#### **Contributions of each author:**

Author 1 - Chunlong Ran.  
Author 2 - Xiangzhe Liu.  
Author 3 - Jiangyan Sun.  
Author 4 - Yanbo Zhang.  
Author 5 - Chen Bai.  
Author 6 - Mengjun Li.