INPLASY PROTOCOL

To cite: Rong et al. Chinese herbal compounds containing scorpion in the treatment of epilepsy： A protocol for systematic review and meta-analysis. Inplasy protocol 202120056. doi: 10.37766/inplasy2021.2.0056

Received: 18 February 2021

Published: 18 February 2021

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Support: **National Natural Science Found.**

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

Conflicts of interest:
None declared.

Chinese herbal compounds containing scorpion in the treatment of epilepsy： A protocol for systematic review and meta-analysis

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Review question / Objective: **This study aims to investigate the effectiveness and safety of Chinese herbal compounds containing scorpion in treating epilepsy.**
Condition being studied: **Epilepsy is one of the common neurological diseases. It can affect about 0.5–1.0% of the population regardless of their race and social class. Despite the development of a wide range of treatments, there remaining about one-third of patients still experience seizures. Chinese herbal compounds containing scorpion (CHCCS) have shown an outstanding curative effect on nerve protection and epilepsy. There's no study to assess its clinical efficacy and safety.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 February 2021 and was last updated on 18 February 2021 (registration number INPLASY202120056).

INTRODUCTION

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treatments, there remaining about one-third of patients still experience seizures. Chinese herbal compounds containing scorpion (CHCCS) have shown an outstanding curative effect on nerve protection and epilepsy. There's no study to assess its clinical efficacy and safety.

METHODS

Participant or population: Patients with diagnosed epilepsy will be included, and there will be no restriction on the type of epilepsy. The patients enrolled regardless of their gender, age, race, and duration.

Intervention: The experiment group used the CHCCS regardless of dosage forms. Besides, CHCCS combined with other effective therapies will also be included.

Comparator: The control group applied for placebo, no cure, drug treatment, or other active therapies.

Study designs to be included: All clinical randomized controlled trials (RCTs) labeled with or without blind method will be included. If less than 5 papers are collected, we will broaden the research criteria to include non-randomized studies and semi-randomized control studies using the Cochrane Effective Practice and Organization of Care (EPOC) approach. The language of literature will be limited to English and Chinese. The animal study, conference papers, case reports.

Eligibility criteria: All clinical randomized controlled trials (RCTs) labeled with or without blind method will be included. If less than 5 papers are collected, we will broaden the research criteria to include non-randomized studies and semi-randomized control studies using the Cochrane Effective Practice and Organization of Care (EPOC) approach. The language of literature will be limited to English and Chinese. The animal study, conference papers, case reports, protocol, comments, supplementary issues, and reviews will be excluded. Patients with diagnosed epilepsy will be included, and there will be no restriction on the type of epilepsy. The patients enrolled regardless of their gender, age, race, and duration. The experiment group used the CHCCS regardless of dosage forms. Besides, CHCCS combined with other effective therapies will also be included. The control group applied for placebo, no cure, drug treatment, or other active therapies. The primary outcome is the efficacy of the CHCCS on treating epilepsy. And the secondary outcomes include recurrence rate and side effects.

Information sources: We will search four Chinese databases (China National Knowledge Infrastructure [CNKI], Wan-fang database, VIP Database, Chinese Biomedical Literature Database [CBM]) and five English databases (PubMed, Web of Science, EMBASE, Cochrane Library, International Clinical Trials Registry Platform [ICTRP]). We will also search the Chinese Clinical Trial Registry Centers and Grey Literature. The retrieval time is limited from database establishment to February 2021. We will contact the author for further information if there is a lack of essential data. We will also search the reference lists of meeting minutes and identified publications. The following literature established earlier than the database in China, such as “China Journal of Traditional Chinese Medicine and Pharmacy,” “Journal of Traditional Chinese Medicine,” and “China Journal of Chinese Materia Medica” will also be searched.

Main outcome(s): The primary outcome is the efficacy of the CHCCS on treating epilepsy.

Additional outcome(s): The secondary outcomes include recurrence rate and side effects.

Quality assessment / Risk of bias analysis: The Cochrane Collaboration’s risk of bias tool will be adopted to assess the risk of bias. For each item, “low,” “unclear,” or “high” will be used as the key to the bias of risk. This work will be carried out by two authors (JY and XW). The final policy decisions will be made by the third author (Dr. Ma) if disagreements appear.

Strategy of data synthesis: RevMan V.5.3.0 will be used to analyze the data. For dichotomous data, the risk ratio with a 95% confidence interval (CIs) will be estimated. For continuous data, we will calculate the mean difference (MD) or standardized mean difference with 95% CIs, depending on whether we use the same scale to measure an outcome in different studies. A P-value .1, I2＜50%, considerable no heterogeneity in the included studies will be confirmed, and the fixed effect model will be applied. If not, a random effect model. We will apply subgroup analysis to investigate the potential clinical heterogeneity. We will perform a systematic review if we cannot find the source of heterogeneity.

Subgroup analysis: According to the differences in the dosage form, dose of the scorpion, type of disease, course of treatment, and patients' age, the subgroup analysis will be performed.

Sensitivity analysis: The robustness of the results should be identified by performing the sensitivity analysis according to the following criteria: sample size, the quality of studies, missing data, and heterogeneity qualities.

Country(ies) involved: China.

Keywords: traditional Chinese medicine, scorpion, epilepsy, systematic review, meta-analysis.

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