INPLASY PROTOCOL

To cite: Yuan et al. Shuanghuanglian injection for Viral pneumonia _ A protocol for meta-analysis. Inplasy protocol 2020120047. doi: 10.37766/inplasy2020.12.0047

Received: 08 December 2020

Published: 08 December 2020

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Support: **Sichuan Provincial Fund.**

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

Conflicts of interest:
None.

Shuanghuanglian injection for Viral pneumonia _ A protocol for meta-analysis

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Review question / Objective: **P: Studies included adults aged 18 years old and older with the diagnosis of viral pneumonia in the general population; I: Shuanghuanglian injection alone or in combination with conventional therapy and/or biological agents; C: no treatment, placebo, and conventional therapy alone; O: Outcomes will include mortality, cure rate, efficacy or adverse events confirmed by imaging diagnosis, or records such as risk ratio, odds ratio, hazard ratios, standardized incidence ratio, standardized mortality ratio and associated 95% confidence intervals (CIs); S: RCTs.**

Condition being studied: **Viral pneumonia is inflammation (irritation and swelling) of the lungs due to infection with a virus . Specific Treatments for the viral pneumonia were not yet determined. Rapidly progressing viral pneumonia is associated with considerable mortality, representing a severe threat and imparting a substantial financial burden worldwide.The current treatment of viral pneumonia is to use antibiotics, mechanical ventilation, vasoactive drugs, nutritional support, etc. There is no effective treatment for viral pneumonia. In recent years, Chinese medical workers in China have used Shuanghuanglian Injection to treat viral pneumonia and have achieved good clinical results.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 December 2020 and was last updated on 08 December 2020 (registration number INPLASY2020120047).

INTRODUCTION

Review question / Objective: **P: Studies included adults aged 18 years old and older with the diagnosis of viral pneumonia in the general population; I: Shuanghuanglian injection alone or in combination with conventional therapy and/or biological agents; C: no treatment, placebo, and conventional therapy alone; O: Outcomes will include mortality, cure rate, efficacy or adverse events confirmed by imaging**

diagnosis, or records such as risk ratio, odds ratio, hazard ratios, standardized incidence ratio, standardized mortality ratio and associated 95% confidence intervals (CIs); S: RCTs.

Rationale: The aim of our study is to objective provide helpful evidence of whether Shuanghuanglian Injection would reduce the mortality and incidence of viral pneumonia. A better understanding of Shuanghuanglian injection, guide the treatment of viral pneumonia.

Condition being studied: Viral pneumonia is inflammation (irritation and swelling) of the lungs due to infection with a virus . Specific Treatments for the viral pneumonia were not yet determined. Rapidly progressing viral pneumonia is associated with considerable mortality, representing a severe threat and imparting a substantial financial burden worldwide.The current treatment of viral pneumonia is to use antibiotics, mechanical ventilation, vasoactive drugs, nutritional support, etc. There is no effective treatment for viral pneumonia. In recent years, Chinese medical workers in China have used Shuanghuanglian Injection to treat viral pneumonia and have achieved good clinical results.

METHODS

Search strategy: #1 search "Viral pneumonia" [Title/Abstract],#2 Search "Shuanghuanglian Injection"[Title/Abstract],#3 Search "RCT" [Title/Abstract] OR "randomized controlled trial" [Title/Abstract],#4 Search "Efficacy" [Title/Abstract] OR "safety" [Title/Abstract],#5 #1 and #2 and #3 and #4.

Participant or population: Adults aged 18 years old and older with the diagnosis of viral pneumonia in the general population.

Intervention: Shuanghuanglian injection alone or in combination with conventional therapy and/or biological agents.

Comparator: No treatment, placebo, and conventional therapy alone.

Study designs to be included: Randomized controlled trails will be included.

Eligibility criteria: Two authors independently complete the following process: according to the above search strategy to complete the process of document retrieval, import documents into EndNote X7 for centralized management. Then, according to the inclusion and exclusion criteria, filter the literature by reading the title and abstract. If it is not possible to determine whether the article meets the requirements based on the inclusion and exclusion criteria, then read the full text to select. In the entire literature screening process, if the 2 authors have different opinions, the third author joins the discussion to get a common opinion.

Information sources: The China National Knowledge Infrastructure, Wanfang Database, Chinese Science and Technology Periodical Database, Chinese Biomedical Literature Database, Pubmed, Embase, Web of Science, and the Cochrane library were searched for randomized clinical trials until 11st of December , 2020.

Main outcome(s): Outcomes will include mortality, cure rate, efficacy or adverse events confirmed by imaging diagnosis.

Additional outcome(s): Risk ratio, odds ratio, hazard ratios, standardized incidence ratio, standardized mortality ratio and associated 95% confidence intervals (CIs).

Data management: The basic process of the included literatures will be determined by referring to the Cochrane Collaboration System Evaluator's Manual (5.1.0). Extracted data included participants (age, sex), interventions(Shuanghuanglian Injection alone or in combination with CT), controls (type, frequency, and duration), outcomes (measures and time points), and study design (randomization, allocation concealment, blinding, and etc). If required information was not reported, we tried to

request it from the corresponding author of the studies.

Quality assessment / Risk of bias analysis: Two researchers independently evaluated the risk of bias in randomized controlled trials in accordance with the Cochrane Handbook of Systematic Reviewers, including the following items: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. The quality of studies was classified as being at of high, unclear, or low risk of bias. After completion, they would recheck. In case of a disagreement, they would discuss. If no agreement could be reached, a decision would be made in consultation with researchers from the third party.

Strategy of data synthesis: When meta analysis is available, RevManV5.3 will be applied to analyze data. Data will use a random effects model with 95% CIs as substantial heterogeneity is expected among included studies. If the I2 test is >75%, we will not perform meta-analysis if the heterogeneity cannot ascertain possible causes from both clinical and methodological diversity. The fixed-effects model will be utilized for data synthesis if the I2 is <50%, while the random-effects model will be performed for data synthesis when the I2 is in the range of 50% to 75%.

Subgroup analysis: If the Chi-squared test and Higgins I2 test detect obvious heterogeneity between studies, we will conduct a subgroup analysis from the following aspects: different types of TCM, treatment time, clinic classification, course of disease, and so on.

Sensibility analysis: In order to ensure the Credibility of the research results, we will conduct a sensitivity analysis of the included literature and will eliminate low quality literature.

Language: The language is limited to Chinese and English.

Country(ies) involved: China.

Other relevant information: This work is supported by Major Frontier Project of China's Sichuan Province Science and Technology Department (2016JY0008)

Keywords: Viral pneumonia, Shuanghuanglian injection, efficacy and safety, meta-analysis, protocol.

Contributions of each author:

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Author 3 - Mingjun Hu - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 4 - Zhilin Si - The author read, provided feedback and approved the final manuscript.
Author 5 - Shuncheng Xie - The author read, provided feedback and approved the final manuscript.
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