INPLASY PROTOCOL

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Conflicts of interest:
None.

Efficacy and safety of Traditional Chinese Medicine Combined with Routine Western Medicine for the asymptomatic novel coronavirus disease (COVID–19) --A Bayesian network meta-analysis protocol

Zhang, W[1]; Zhu, X[2]; Sun, Y[3].

Review question / Objective: **Is it safe and effective to treat asymptomatic COVID–19 with Traditional Chinese Medicine Combined With Routine Western Medicine ? What are the differences among Routine Western medicine alone and Traditional Chinese Medicine Combined with Western Medicine .Which plan is the most effective?**
Condition being studied: **COVID–19 has become a common problem worldwide now. Stopping it from spreading has become the most crucial task at the moment. Because asymptomatic patients are infectious, asymptomatic infections need to be taken seriously. At present, there is no perfect plan for the treatment of COVID–19. Most of them are antiviral and symptomatic treatments, and the clinical efficacy is not good. Especially for asymptomatic patients, there is a lack of effective treatment. The principle of traditional Chinese medicine to treat diseases is to improve the ability to resist viruses, rather than aiming at clinical symptoms, so it has advantages for asymptomatic COVID–19 patients. At present, traditional Chinese medicine has achieved good results in the fight against the epidemic in China, but there is no international research on the systematic evaluation of the clinical efficacy of integrated traditional Chinese and western medicine in the treatment of asymptomatic COVID–19 infections.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 July 2020 and was last updated on 07 July 2020 (registration number INPLASY202070022).

INTRODUCTION

Review question / Objective: **Is it safe and effective to treat asymptomatic COVID–19 with Traditional Chinese Medicine Combined With Routine Western Medicine ? What are the differences among Routine Western medicine alone and Traditional Chinese Medicine Combined with Western Medicine .Which plan is the most effective?**

Rationale: Traditional Chinese medicine has advantages in treating COVID–19, especially asymptomatic infection, and has achieved remarkable results. It alleviates the plight of the lack of treatment methods, but there is currently no systematic analysis of traditional Chinese medicine in the treatment of asymptomatic COVID–19.

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METHODS

Search strategy: We will use a combination of Medical Subject Heading, and free-text terms with various synonyms.There will be no restrictions on date , country, publication status, or year of publication.

Participant or population: Patients diagnosed with asymptomatic COVID–19 infection. Patients with asymptomatic COVID–19 are those who have no relevant clinical symptoms but have a positive pathogenic test of respiratory tract specimens for COVID–19.

Intervention: The treatment group must have been treated with traditional Chinese medicine in combination with routine Western medicine.

Comparator: Conventional western medicine treatment, such as antiviral drugs.

Study designs to be included: All relevant RCTs of traditional Chinese medicine for asymptomatic COVID-19 published in Chinese or English will be included.

Eligibility criteria: We included studies if they meet the following criteria: 1) The participants was diagnosed as asymptomatic COVID-19; 2) The intervention was treated with traditional Chinese medicine in combination with routine western medicine; 3) The control group was treated with conventional western medicine 4) Study types were Randomized controlled trials.

Information sources: We will comprehensively search the following electronic databases: Cochrane Library, PubMed, Web of Science, EMBASE, Chinese Biomedical Literature Database (SinoMed), Chinese National Knowledge Infrastructure (CNKI), Wanfang database and VIP database from December 2019 to now. We will also search ongoing trial registers in the trial registry websites.

Main outcome(s): Because the patients included in the study had no obvious symptoms, the main outcomes were safety and prognostic indicators, including the time when the nucleic acid turned negative, the proportion of patients with disease progression, changes in laboratory indicators, and side effects of drugs.

Quality assessment / Risk of bias analysis: Two researchers will independently evaluate the quality of each included trial according to the Cochrane Risk of Bias Tool recommended by Cochrane Handbook Version 5.1.0. Evaluation criteria includes seven items and each aspect will be categorized as “low” “high” or “unclear”. In the process of evaluation, if there are disagreements, they will be resolved through discussion or a third reviewer.

Strategy of data synthesis: First, we will conduct pairwise meta-analyses for direct evidence. Odds Ratio (OR) will be used for dichotomous data and Mean Difference (MD) or Standardized Mean Difference (SMD) for continuous data. The 95% credible interval (CI) of each effect size will be calculated. We will use I2 test to assess statistical heterogeneity. Then we will perform a Bayesian network meta-analysis model for each outcome to estimate the overall treatment effects.

Subgroup analysis: If there is enough evidence, we will conduct subgroup analysis to explore the sources of heterogeneity. The following aspects will be used: age, surgical treatment or not, course of treatment.

Sensibility analysis: Sensitivity analysis was conducted by excluding outliers.

Country(ies) involved: China.

Keywords: asymptomatic COVID–19, network meta-analysis, protocol, traditional Chinese medicine.

Contributions of each author:
Author 1 - Jiahao Wang - Jiahao Wang were responsible for the conception and design, drafting of the manuscript, critical revision of the manuscript for important intellectual content, approval of the final version to be published and agreement to be accountable for all aspects of the work.
Author 2 - Xue Zhu.
Author 3 - Yuying Sun.