

INPLASY PROTOCOL

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Corresponding author:
Yunze Wang

yunzewangwww@163.com

Author Affiliation:
Pharmacy College, Shaanxi
University of Chinese Medicine

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The authors declare that they have no conflict of interest.

The Curative Effect of Reduning Injection Combined with Xuanfeibaidu Formula on COVID-2019: A protocol for systematic review and meta analysis

Wang, Y¹; Han, L²; Zhang, W³; Sun, J⁴.

Review question / Objective: Reduning injection is an important traditional chinese medicine injection for the treatment of COVID-2019. It is mainly used for the symptoms of high fever, headache, cough, and other symptoms caused by upper respiratory infection (URI). Xuanfeibaidu formula can inhibit virus infection and replication, this formula possessed anti-inflammatory effect and adjust the body's immunological function after virus infection cells. The project aims to treat COVID-2019 by combining Reduning injection with Xuanfeibaidu Formula.

Condition being studied: The studies will be searched from the China national knowledge infrastructure (CNKI), wanfang database, Chinese science and technology periodical database, medline/pubmed, and the cochrane library. The suitable articles, about Reduning injection with Xuanfeibaidu for COVID-2019, will be comprehensively and systematically searched without limitations of regions or language Formula. Electronic database retrieval will be supplemented by manual retrieval of the included article reference list.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 September 2020 and was last updated on 09 September 2020 (registration number INPLASY202090039).

INTRODUCTION

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METHODS

Participant or population: The therapeutic effect of Reduning injection combined with Xuanfeibaidu Formula was compared to use of Reduning injection alone about the treatment of COVID-2019.

Intervention: The treatment group was treated with Reduning injection combined with Xuanfeibaidu Formula.

Comparator: The control group was treated with Reduning injection alone.

Study designs to be included: All included studies was Relevant randomized controlled trials (RCTs).

Eligibility criteria: According to Treatment protocols for COVID-19 (Trial Version 8) and suggestion of a clinical specialist, we screened the full-text article of relevant abstracts, design and select the following criteria as the basis for inclusion: (1) Patients (belong to RCTs) were diagnosed as COVID-2019 and meet the diagnostic criteria for COVOD protocol. (2) All the selected methods are RCTs. (3) The experimental group was treated with Reduning injection and Xuanfeibaidu Formula, while the control group was treated with Reduning injection alone. (4) The selection criteria for each study must include at least two of the following

criteria: $RR \geq 30$ beats/min; ARDS (such as $OI < 300$ mmHg); VALI, such as diffuse alveolar injury or exudative alveolitis; Lymphnode lymphocyte; white blood cell (WBC); MIS-C; immunoglobulin G (IgG), immunoglobulin M (IgM); thromboembolism including IL-1 β , TNF- α , IL-8; lung CT.

Information sources: The China national knowledge infrastructure (CNKI), Wanfang database, Chinese science and technology periodical database, Medline/Pubmed, and the Cochrane library.

Main outcome(s): The total effective rate, the main clinical feature disappearance rate, and the minor symptom disappearance rate were regarded as binary variables. Descriptive summary statistics in the form of mean, standard deviation, and range for continuous parametric measures were analyzed. Results will be calculated as mean difference (MD) and 95% CI. Dichotomous outcomes will be calculated with the odds ratio (OR) and 95% CI. Contents of inflammatory cytokines (IL-6, CRP, FER, TNF- α , WBC, IgG, IgM) are continuous variables, using weighted mean difference (WMD) or standardized mean difference (SMD) as the effect index, and 95% CI for description. The Q test was used for analysis, combined with I² to quantitatively determine the degree of heterogeneity. If $P \geq 0.1$ and $I^2 < 50\%$, it is considered that there is no statistical heterogeneity.

Quality assessment / Risk of bias analysis: We used the Cochrane bias risk assessment to assess the methodological quality, random sequence generation, allocation concealment, the blinding method for patients, researchers and outcomes assessors, incomplete result data, selective reports, and other sources of bias. Each item will be rated as high, low or unclear risk of bias. We included all available studies to maximize the sample size and to enhance the generalizability of our findings.

Strategy of data synthesis: We will examine the publication bias by evaluating the

symmetry of the funnel plot. If the funnel plot is not symmetric, the results of the study may have a publication bias. If there is significant heterogeneity in our study, we will perform a subgroup analysis based on the type of control group. The experimental information in the study is incomplete, incomplete outcome data, and selective reports cannot judge the risk of bias.

Subgroup analysis: If there is significant heterogeneity in our study, we will perform a subgroup analysis based on the type of control group. Subgroup analyses by the statistical differences between the studies qualitative, critical illness rate, sample size, and quality score were performed.

Sensibility analysis: Two independent authors read the title, abstract, and full text of the literature according to the inclusion criteria, excluded low-quality studies, and cross-checked by two authors.

Language: No language restrictions.

Country(ies) involved: China.

Keywords: Meta-analysis; COVID-2019; Reduning injection; Xuanfeibaidu Formula.

Contributions of each author:

Author 1 - Yunze Wang - Collect and select literature drafted the manuscript.

Author 2 - Lizhu Han - Performed the data extraction.

Author 3 - Wei Zhang - Analyzed the data.

Author 4 - Jing Sun - Check and Designed the study, amended the paper.