INPLASY PROTOCOL

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Support: **None.**

Review Stage at time of this submission: **Formal screening of search results against eligibility criteria.**

Conflicts of interest:
None declared.

A meta analysis on the efficacy of Chengqi Decoction in the treatment of ARDS/ALI

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Review question / Objective: **What is the clinical efficacy of combing Chengqi Decoction in the treatment of ARDS/ALI, compared with the conventional treatment of ARDA/ALI with western medicine?**
Condition being studied: **Acute respiratory distress syndrome(ARDS), Acute lung injury(ALI).**
Eligibility criteria: **(1) lacking literature data (e.g., nonpaired studies) (2) duplicate publications; (3) do not have access to the full text (4) conference reports, system reviews, protocols, or abstracts; (5) RCTs with small sample sizes; . (5)The treatment course is less than 6 days (6) Exclude articles with high risk of deviation**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 August 2022 and was last updated on 12 August 2022 (registration number INPLASY202280040).

INTRODUCTION

Review question / Objective: **What is the clinical efficacy of combing Chengqi Decoction in the treatment of ARDS/ALI, compared with the conventional treatment of ARDA/ALI with western medicine?**

Condition being studied: **Acute respiratory distress syndrome(ARDS), Acute lung injury(ALI).**

METHODS

Search strategy: **The databases of Cochrane central register of controlled trials (CENTRAL, present), Embase**

(inception to present), MEDLINE (inception to present), PUBMED (inception to present), Web of Science (SCI; inception to present) and four Chinese database Chinese biomedical literature database (CBM; inception to present), China national knowledge infrastructure (which includes inception to present), and Wanfang Data (WANFANG;inception to present) will be searched for the related trial. We used the following keywords and their variations: “Acute respiratory distress syndrome”, “acute”, “respiratory”, “distress next syndrome” and “ARDS ”,"ALI", "Chengdu decoction", "Dahuang" ,"Taoren decoction", "Xuanbai Chengdu decoction", "Xiao Chengdu decoction", "Xiexia decoction", Fu shi rejie". The search strategy will be presented through the search flow chart and the search term table.

Participant or population: Adult patients (older than 18 years old) who were diagnosed with ALI/ARDS defined by American-European Consensus Conference (AECC) in 1994 and Berlin definition (2012) were included, with no language and country restriction.

Intervention: The control group was treated with conventional western medicine for ARDS/ALI, such as anti infection, auxiliary ventilation or prone position. The experimental group was treated with traditional Chinese medicine on the basis of conventional western medicine. Intervention related to Chengqi Decoction (such as Tongfu method, rhubarb, purgative method) will be included, and The experimental group that is other chinese medicine or not Chengqi Decoction will be excluded. And treatment less than 7days will also be excluded. For example, on the basis of routine treatment (anti infection, nerve block, auxiliary ventilation, prone position and other Western medicine treatment), the experimental group used Dachengqi Decoction, which was administered through gastric tube once every 12 hours for 7 days. Then observe the changes of clinical indicators after 7 days.

Comparator: The control group was treated with conventional western medicine for ARDS/ALI, such as anti infection, auxiliary ventilation or prone position.

Study designs to be included: Randomized Clinical Trials. The studies of any other types will be excluded, such as case reports, conference reports, system reviews, protocols, or abstracts; For some Chinese articles, we mainly include articles in national or local funded research projects or high-quality journal.

Eligibility criteria: (1) lacking literature data (e.g., nonpaired studies) (2) duplicate publications; (3) do not have access to the full text (4) conference reports, system reviews, protocols, or abstracts; (5) RCTs with small sample sizes; . (5)The treatment course is less than 6 days (6) Exclude articles with high risk of deviation.

Information sources: The databases of Cochrane central register of controlled trials (CENTRAL, present), Embase (inception to present), MEDLINE (inception to present), PUBMED (inception to present), Web of Science (SCI; inception to present) and four Chinese database Chinese biomedical literature database (CBM; inception to present), China national knowledge infrastructure (which includes inception to present), and Wanfang Data (WANFANG;inception to present) will be searched for the related trials. In order to improve the quality of the collected articles, we mainly search for articles in national or local funded research projects or core journals in the Chinese database. For some papers with missing data, we will sincerely ask the author by email.

Main outcome(s): Primary outcomes include mortality, parameters of mortality, intensive care unit (ICU) stay, IL-6, TNF-α, oxygenation Index (PaO2/FiO2, we only recorded the changes of Oxygenation Index before and after seven days of treatment if studies reported Oxygenation Index at different time points).

Additional outcome(s): Secondary outcomes include the length of ICU stay, mechanical ventilation duration.

Data management: Two authors will independently extract information from the included RCTs. The information include author, type, published year, male/female, country, contral group, intervention (chinese medcine, frequnecy, the cource of treament, route of administration), sample size, age, outcome, APAC-HE, indications. If the data are missing, wrong, or unclear, the original authors will be contacted to inquire about it. Any other diverge regarding the data collection and management will be resolved by a third reviewer involved through discussion.

Quality assessment / Risk of bias analysis: The Cochrane Handbook for Systematic Reviews of Interventions tool will be used to assess the risk of bias of all included RCTs. This tool includes severe domains covering the random sequence generation, allocation concealment, subjects, investigators and outcome assessor blinding, incomplete results data, selective results reporting, and other bias. Two authors will independently evaluate the quality of each included RCT, and the disagreement will be resolved by discussion with a third author. We will visually explain the results of the evaluation of these seven projects through the bar scale chart, and we will draw graphs like the following chart.

Strategy of data synthesis: As for enumeration data, the risk ratio (RR) will be presented. As for continuous data, it will be presented by mean difference (MD) and 95% confidence intervals (CIs). If the measurement tools are not the same, the data will be converted to the standardized mean difference (SMD) and 95% CIs. If the heterogeneity is not significant, a meta-analysis will be carried out using RevMan 5.3 software, and a fixed-effect model will be used to pool the data. Otherwise, a random-effect model will be applied, and subgroup analysis or sensitivity analysis will be carried to analyze the reasons that cause the heterogeneity. If the heterogeneity remains significant, a narrative summary will be performed.

Subgroup analysis: Subgroup analysis will be conducted according to the different interventions, controls and outcome measurements.

Sensitivity analysis: Where appropriate, sensitivity analysis will be carried out to eliminate the impact of low-quality studies, and also to evaluate the robustness of the results based on the methodological qualities, and statistical models.

Language restriction: None.

Country(ies) involved: China.

Keywords: Meta-analysis, ARDS/ALI, Chengqi Decoction, mortality, IL-6, TNF-α, oxygenation Index (PaO2/FiO2, intensive care unit (ICU) stay.

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