INPLASY PROTOCOL

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

Conflicts of interest: **No.**

Efficacy of spironolactone for acute heart failure: a protocol for systematic review

Feng, YL[1]; Lu, M[2].

Review question / Objective: **Is spironolactone effective for the treatment of acute heart failure (AHF)?**
Condition being studied: **Spironolactone; acute heart failure.**
Information sources: **This study will search all potential studies in PUBMED, EMBASE, Cochrane Library, Web of Science, CINAHL, CBM, CNKI and VIP database from initial through July 1, 2020. A specific description of search strategy of PUBMED is built. We will modify similar search strategies and will apply them to other electronic databases. Additional searches will be conducted from any associated sources, such as conference proceedings, thesis, dissertations, and reference lists of relevant reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 July 2020 and was last updated on 14 July 2020 (registration number INPLASY202070053).

INTRODUCTION

Review question / Objective: **Is spironolactone effective for the treatment of acute heart failure (AHF)?**

Condition being studied: **Spironolactone; acute heart failure**

METHODS

Participant or population: **All patients who were diagnosed as AHF will be included in this study, irrespective gender, age, economic status, and other information.**

Intervention: We will include any forms of spironolactone in treating patients with AHF.

Comparator: We will consider any therapies in treating AHF. However, we will exclude combined treatments with spironolactone.

Study designs to be included: This study will identify all potential randomized controlled trials (RCTs) on efficacy and safety of spironolactone in treating AHF.

Eligibility criteria: This study will identify all potential RCTs on efficacy and safety of spironolactone in treating AHF, in spite of language and publication time.

Information sources: This study will search all potential studies in PUBMED, EMBASE, Cochrane Library, Web of Science, CINAHL, CBM, CNKI and VIP database from initial through July 1, 2020. A specific description of search strategy of PUBMED is built. We will modify similar search strategies and will apply them to other electronic databases. Additional searches will be conducted from any associated sources, such as conference proceedings, thesis, dissertations, and reference lists of relevant reviews.

Main outcome(s): Outcomes are all-cause mortality, clinical congestion score, urine output, weight change, quality of life, and safety.

Data management: Two researchers will independently extract main data from several aspects: author, time of publication, country, study design, study setting, sample size, gender, age, diagnostic criteria, inclusion and exclusion criteria, treatment details, comparators, frequency, dosage, outcomes, and adverse events. We will solve any disagreements between two researchers with the help of another researcher.

Quality assessment / Risk of bias analysis: Two researchers will appraise study quality using Cochrane risk of bias tool via 7 domains. If any different views occur, another experienced researcher will help to solve them through discussion.

Strategy of data synthesis: This study will utilize RevMan 5.3 software to perform data analysis. The dichotomous data will be presented as risk ratio and 95% confidence intervals (CIs), and continuous data will be estimated as mean difference or standardized mean difference and 95% CIs. The statistical heterogeneity across eligible trials is examined by I^2 test. If there is few heterogeneity ($I^2 \leq 50\%$) among sufficient eligible studies on the same outcome, data will be pooled using a fixed-effect model, and meta-analysis will be performed. If there is obvious statistical heterogeneity across included studies ($I^2 > 50\%$), its sources will be identified using subgroup analysis. If we can not examine sources of obvious heterogeneity, we will perform descriptive analysis instead of meta-analysis.

Subgroup analysis: We will explore source of obvious heterogeneity based on the study information, patient characteristics, study quality and outcomes.

Sensibility analysis: We will employ sensitivity analysis to test robustness of merged outcome results by excluding studies with high risk of bias.

Country(ies) involved: China.

Keywords: Spironolactone; acute heart failure; efficacy; safety.

Contributions of each author:
Author 1 - Yan-lin Feng.
Author 2 - Min Lu.