INPLASY PROTOCOL

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None declared.

Effects of oral Omecamtiv Mecarbil in patients with heart failure and a reduced ejection fraction: a systematic review and meta-analysis of randomized controlled trials

Jin, XD[1]; Wu, H[2]; Cui, M[3]; Wei, LP[4]; Qi, X[5].

Review question / Objective: **The aim of this systematic review is to compare Oral Omecamtiv mecaril and Placebo in terms of efficacy and safety in the HF to better inform clinical practice. To this end, the proposed systematic review will address the following question: Which is the best choice to reduce the endpoint Outcome in HF, Oral Omecamtiv mecaril or Placebo ?**
Condition being studied: **The following outcomes were of involvement: the combined endpoint of cardiovascular death and HF hospitalisation ; CV death; first time HF hospitalisation; first HF event, all-cause death, and changes in cardiac function after treatment, the Kansas City Cardiomyopathy Questionnaire (KCCQ) clinical summary score the proportion of patients who improved, In addition, safety outcomes of involvement include relating-medication adverse effects, major adverse outcomes, ventricular arrhythmias, myocardial ischaemia, cardiac infarction.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 May 2022 and was last updated on 11 May 2022 (registration number INPLASY202250068).

INTRODUCTION

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METHODS

Participant or population: The population in this analysis consisted of patients (age between 18 and 85 years) with HF signs and symptoms (defined as New York Heart Association symptom class II-IV) with a left ventricular ejection fraction ≤40%.

Intervention: Oral Omecamtiv mecaril.

Comparator: Placebo.

Study designs to be included: RCT.

Eligibility criteria: Following the abstract assessment, articles in English which have been prospective randomised controlled trials (RCTs) administring oral OM in HF patients were chosen for full article review.

Information sources: Searched in four electronic databases (Embase, PubMed, Cochrane, and Web of Science).

Main outcome(s): Efficacy and safety.

Quality assessment / Risk of bias analysis: The Institute of Medicine standards were enabled to identify the strength of the evidence, and the Cochrane Collaboration Risk of Bias Assessment Tool was used to assess risk of bias, the degree of proof for every essay was graded as low, median, or high through using this standardised tool, Two impartial commentators allocated a degree of bias.

Strategy of data synthesis: Review Manager (RevMan) 5.4 was used to conduct data analysis. On the statistics from chosen RCTs, a meta analysis was performed, According to standard methods (https://handbook.cochrane.org), When no measurable heterogeneity was discovered, fixed effects model (FEM) analysis (Mantel-Haenszel method) was performed to calculate risk ratios (RRs) for binary data with 95 percent confidence intervals (CI) for categorical data and Mean ± Standard Deviation for continuous results difference. Random effects model (REM) analysis (DerSimonian-Laird) methods were utilized when there was evidence of significant heterogeneity. Chi-square ($\chi 2$) and index of inconsistency (I2)were used to determine the degree of heterogeneity between trials, with $I2 > 50\%$ representing the existence of remarkable heterogeneity. Publication bias was explored via funnel charts and Egger intercept tests (p-values 0.1 for significant asymmetry) with p-values less than 0.05 indicating statistical significance.

Subgroup analysis: Divided into two subgroups according to different medications.

Sensitivity analysis: Publication bias was explored via funnel charts and Egger intercept tests (p-values 0.1 for significant asymmetry) with p-values less than 0.05 indicating statistical significance.

Language: Only randomized clinical trials published in English will be considered for inclusion.

Country(ies) involved: China.

Keywords: Heart Failure: Oral Omecamtiv mecaril: Efficacy and safety.

Contributions of each author:
Author 1 - Xiandu Jin - Author 1 drafted the manuscript.
Author 2 - Hao wu.
Author 3 - Min Cui.
Author 4 - Liping Wei.
Author 5 - Xin Qi.