INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Effect of iron therapy for the patients of Pulmonary arterial hypertension: A systematic review and meta-analysis

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Review question / Objective: **1.Population: Patients diagnosed with pulmonary hypertension (Pulmonary arterial hypertension was defined as a mean pulmonary-artery pressure of 25 mm Hg or more and a pulmonary-capillary wedge pressure of 15 mm Hg or less at rest); 2.Intervention: Iron Compounds: The intervention group was given standard treatment plan containing iron, while the control group was given the standard treatment plan without iron; 3.Outcomes: The primary end point is the change from baseline to week 12 in the capacity from 6-min walk distance (6MWD); The secondary end points are the difference of mean pulmonary artery pressure and incidence of moderate to severe tricuspid regurgitation between before and after 12 weeks of treatment; 4.Study design: Randomized controlled trial (RCT).**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 June 2021 and was last updated on 27 June 2021 (registration number INPLASY202160101).

INTRODUCTION

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The primary end point is the change from baseline to week 12 in the capacity from 6-min walk distance (6MWD); The secondary end points are the difference of mean pulmonary artery pressure and incidence of moderate to severe tricuspid regurgitation between before and after 12 weeks of treatment; 4.Study design: Randomized controlled trial (RCT).

Condition being studied: Iron is well tolerated and effective in patients with pulmonary hypertension and iron deficiency anemia. At present, some studies have confirmed that iron can improve 6-minute exercise tolerance in patients with pulmonary hypertension, but no meta analysis has confirmed this conclusion.

METHODS

Participant or population: Patients diagnosed with pulmonary hypertension.

Intervention: Iron Compounds.

Comparator: Patients with pulmonary hypertension treated with iron compoundsiron.

Study designs to be included: Randomized controlled studies.

Eligibility criteria: We will include these studies if they meet the following condition 1.Randomized controlled trial (RCT); 2.Patients diagnosed with pulmonary hypertension (Pulmonary arterial hypertension was defined as a mean pulmonary-artery pressure of 25 mm Hg or more and a pulmonary-capillary wedge pressure of 15 mm Hg or less at rest); 3.The intervention group was given standard treatment plan containing iron, while the control group was given the standard treatment plan without iron; 4.The minimum follow-up period was 12 weeks. The exclusion criteria was: 1.Non-RCTs; 2. Animal experimental research literature; 3. Literature review and meta analysis; 4. Literature with unclear sources; 5. Repeated publications; 6. literature that cannot obtain the original data.

Information sources: PubMed, EMBASE (include MEDLINE), Cochrane Central Register of Controlled Trial, Web of Science, China National Knowledge Infrastructure(CNKI), WangFang Database, VIP, SinoMed.

Main outcome(s): 6-min walk distance (6MWD).

Additional outcome(s): 1.mean pulmonary artery pressure (mPAP); 2.The incidence of moderate to severe tricuspid regurgitation.

Quality assessment / Risk of bias analysis: We will use Cochrane risk of bias assessment tool version 2.0 (RoB 2.0) to assess the risk of bias of RCTs.

Strategy of data synthesis: We will use Revman 5.3 statistical software and Stata 14.0 for meta-analysis of the literature. Firstly, the heterogeneity test will be conducted on the research data. If the heterogeneity test $p > 0.1$ and $I2 \leq 50\%$, it will be considered that there have no heterogeneity between the studies, and the fixed effect model will be selected to calculate the combined amount. When the heterogeneity is large, sensitivity analysis will be carried out to find the source of heterogeneity. If the results are still heterogeneous, random effect model will be selected to calculate the combined amount. Relative risk (RR) will be used as the effect quantity index for binary variables, and mean difference (MD) or standardized mean difference (SMD) will be used as the effect quantity index for continuous variables.

Subgroup analysis: No.

Sensitivity analysis: We will do sensitivity analysis by deleting references one by one.

Country(ies) involved: China.

Keywords: Iron, Pulmonary arterial hypertension.

Contributions of each author:

Author 1 - Peng Wen.
Author 2 - Zou JunFeng.
Author 3 - Tang Feng.
Author 4 - Zheng DeDong.