Medicine (Baltimore). 2020 Aug 28;99(35):e21858. doi: 10.1097/MD.0000000000021858.

A randomized controlled trial study protocol of modified Mahuang-Fuzi-Xixin decoction in the treatment of patients with mild bronchial asthma during acute exacerbation

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PMID: 32871910 PMCID: PMC7458185 DOI: 10.1097/MD.0000000000021858

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Abstract

Introduction: These years, due to dissatisfaction with western medicine treatments, traditional Chinese medicine (TCM) becomes a main treatment for bronchial asthma patients. Lung and kidney yang deficiency syndrome is a common type of asthma and the Chinese herbal medicine formula modified Mahuang-Fuzi-Xixin (MFX) decoction is prescribed for mild bronchial asthma patients with acute exacerbation syndrome. However, there is not obvious evidence to support the efficacy and safety of modified MFX decoction the efficacy and safety to treat mild bronchial asthma and the mechanism of this disease is still unclear.

Methods: A double-blind, placebo-controlled, randomized clinical trial was proposed by us. After a 10-day run-in period, 180 eligible objects will be recruited in this study. These subjects will be allocated to the experimental group or control group in a 1:1 ratio. Patients in the experimental group will take modified MFX decoction. At the same time, patients in the control group will receive a matched placebo. The budesonide inhalation powder will be used as a western medicine treatment for both groups. All subjects will receive 14 days of treatment and another 6 months of follow-up. The primary outcome is the mean change in peak expiratory flow rate from the baseline to 14 days in this research. The secondary outcome includes forced expiratory volume in one second, asthma control test score, Asthma Quality of Life Questionnaire score, curative effect of TCM syndrome, and salbutamol dosage. This trial will also explore the association between the change of immunoglobulin E and modified MFX decoction treatment. Any side effects of the treatment will be recorded.

Discussion: The results of this trial will provide the evidence for the effect of modified MFX decoction in patients with mild bronchial asthma during acute exacerbation. It also will explore the mechanism of this formula in the treatment of bronchial asthma, which will provide another treatment option for patients with mild bronchial asthma.

Figures

Figure 1 5 SPIRIT figure of enrollment, interventions,...

Figure 2 5 Flow chart of the study...

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