Evaluation of efficacy and safety of Qiangzhu-qinggan formula as an adjunctive therapy in adult patients with severe influenza: study protocol for a randomized parallel placebo-controlled double-blind multicenter trial

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Study protocol

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Abstract

Background: Influenza can fall into three categories according to severity: mild influenza, severe influenza, and critical influenza. Severe influenza can result in critical illness and sometimes death particularly in patients with comorbidities, advanced age, or pregnancy. Neuraminidase inhibitors (NAIs) are the only antiviral drugs in widespread use for influenza. However, the effectiveness of NAIs against severe influenza is uncertain. New effective drugs or regimens are therefore urgently needed. Qiangzhu-qinggan (QZQG) formula has been found to be effective against influenza virus infection during long-term application in China, which lacks support of evidence-based clinical trial till now. This study is designed to assess the efficacy and safety of QZQG formula as an adjuvant therapy in adult patients with severe influenza.

Methods: This protocol is drawn up in accordance with the SPIRIT guidelines and CONSORT Extension for Chinese herbal medicine formulas. This is a randomized, placebo-controlled, double-blind, multicenter trial. 228 adults with severe influenza are randomly assigned in a 1:1 ratio to QZQG or placebo for 7 days and receive 1 day of screening, 7 days of intervention and 21 days of observation. The primary outcome is the proportion of clinical improvement, defined as the proportion of patients who met the criteria of 3 points or less in the seven-category ordinal scale or 2 points or less in National Early Warning Score 2 within 7 days after randomization.

Discussion: This is the first randomized, controlled, parallel, double-blind clinical trial to evaluate the efficacy and safety of traditional Chinese herbal formula granules as an adjuvant therapy in adult patients with severe influenza. This study aims to redefine the value of traditional Chinese herbal medicines in the treatment of virus-related respiratory infectious diseases and serves as an example of evidence-based clinical trials of other Chinese herbal medicines.

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- Appendix1InformedConsentForm.pdf
- Appendix2SPIRITChecklistforProtocol.pdf