Binafuxi Granules in the treatment of common cold with heat syndrome based on traditional Uighur medicine: study protocol for a multicenter randomized controlled trial

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Method Article

Keywords:

Posted Date: October 28th, 2018

DOI: https://doi.org/10.21203/rs.1.5/v1

Version of Record: A version of this preprint was published on March 29th, 2019. See the published version at https://doi.org/10.1186/s13063-019-3290-y.

Abstract

Background Common cold is a highly prevalent illness with significant impact on society and health care. Common cold with heat syndrome (CCHS) is one of most common type based on traditional Uighur medicine (TUM) syndrome differentiation, which is widely used in Central Asia. This study is designed to explore the efficacy, safety and optimal therapeutic dosage of Binafuxi Granules in treating CCHS. Methods This is a multicenter, randomized, double-blind, placebo-controlled, phase II clinical trial. A total of 240 patients will be recruited from 5 centers across China and randomly assigned to the high-dose group, low-dose group or placebo control group in a 1:1:1 ratio. All subjects will receive test drugs twice daily for 3 days. The primary outcome is the time to fever relief. Secondary outcomes include the time to fever clearance, duration of primary symptoms and each symptom, change in TUM symptom score. Discussion This is the first placebo-controlled randomized clinical trial for a Uighur medicine in treating common cold. It will provide robust evidence on the efficacy and safety of Binafuxi Granules in the treatment of CCHS. Trial registration The registration number is ChiCTR-IIR-17013379, which was assigned by the Chinese Clinical Trial Registry on 14 November 2017.

Figures

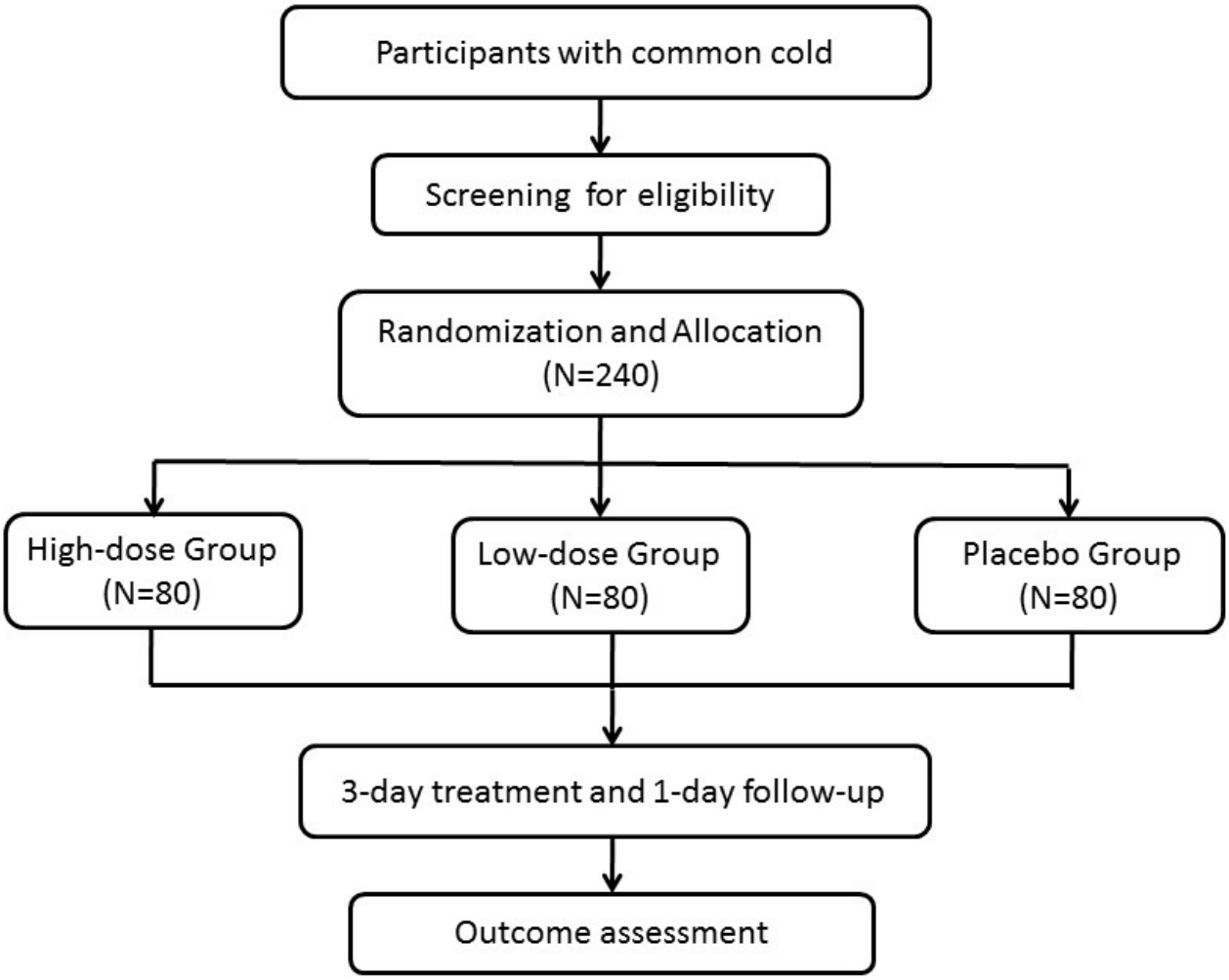

Figure 1

Flowchart. 240 patients will be recruited and randomly allocated to one of three groups (high-dose group = 80; low-dose group = 80; control group = 80). After 3 days, we will analyze the data and make assessment.

	Study Period		
	Enrollment	Allocation	Close-out
Visits	**Visit 1**	**Visit 2**	**Visit 3**
Time point	**Day 0**	**Day 1**	**Day 4**
Basic medical record			
Informed consent	×		
Demographic information	×		
Medical history	×		
Comorbidity	×		
Combined medication	×	×	×
Physical examination	×	×	×
Eligibility screen	×		
Efficacy assessment			
The time to fever relief			×
The time to fever clearance			×
Duration of symptoms			×
TUM symptom score		×	×
Safety assessment			
Vital signs	×		×
Routine blood test	×		×
Urinalysis	×		×
Stool routine	×		×
Liver function test	×		×
Renal function test	×		×
Electrocardiogram	×		×
Chest X-ray	×		×
Urine pregnancy test	×		×
Adverse event record			×
The Others			
Drug distribution		×	
Drug recycling and count			×

Figure 2

Study schedule and SPIRIT figure

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