Comparison of Buyang Huanwu Granules and Naoxintong Capsules in Treatment of Stable Angina Pectoris: Rationale and Design of a Randomized, Double-blind, Multicenter Clinical Trial

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Study protocol

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Abstract

Background: Stable angina pectoris (SAP) is seriously threatened the health of human life currently, and the mortality is in a continuous rising stage. The current treatment strategies mainly include pharmaceutical therapy and revascularization. In China, Buyang Huanwu granules (BYHW) and Naoxintong capsule (NXT) have been used in the treatment of SAP, but it is not clear which one is better in terms of relieving symptoms and improving quality of life. Therefore, we design a clinical trial to compare the efficacy and safety between NXT and BYHW in the treatment of SAP.

Methods: This is a randomized, double-blinded, parallel controlled, multicenter clinical trial protocol. On the basis of western medicine standardized treatment, a total of 128 SAP patients will be randomly divided into intervention group 1 (NXT group), intervention group 2 (BYHW group) and control group (placebo group) at a 2:1:1 ratio. A 2-week run-in period is required prior to randomization, and 1-week baseline period and 4-week treatment period are included in this study. The primary outcome is the efficacy rate of stable angina symptom score improvement; the secondary outcomes include the effect of electrocardiogram, Seattle Angina Questionnaire scores, and the nitroglycerin consumption.

Discussion: This study will evaluate the efficacy and safety between NXT and BYHW in the treatment of SAP. The results will provide critical evidence of the Chinese herbal medicine for SAP.

Trial registration: Chinese Clinical Trials Registry ChiCTR1800015191. Registered on 13 March 2018. http://www.chictr.org.cn/showproj.aspx?proj=25818

Full Text

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Tables

Table 1. Characteristics of the Investigational Product

Study drug 1: Naoxintong Capsule
♦ Ingredients: *Astragalus mongholicus* Bunge [Fabaceae; Radix Astragali], *Hirudo nipponia* Whitman [Hirudinidae; Whitmania pigra Whitman], *Boswellia carteri* Birdw., [Burseraceae; Boswellia carterii], *Commiphora myrrha (T.Nees) Engl.,* [Burseraceae; Myrrha], *Salvia miltiorrhiza* Bunge [Lamiaceae; Salviae Miltiorrhizae Radix Et Rhizoma], *Achyranthes bidentata* Blume [Amaranthaceae; Achyranthes], *Neolitsea cassia* (L.) Kosterm. [Lauraceae; Cassia Twig], *Morus alba* L. [Moraceae; Mulberry Twig], *Spatholobus suberectus* Dunn [Fabaceae; Caulis Spatholobi], *Buthus martensii* Karsch [Buthidae; Scorpion];
♦ Property: capsule; the contents are brown to black brown powder; bitter in taste;
♦ Specification: 0.4g/ capsule;
♦ Bach number: 200593.
Placebo 1: Capsule placebo
♦ Ingredients: corn starch, silica, caramel (liquid), 2% NXT powder and sunset yellow;
♦ With identical color, specification, packaging, property of contents and other features with Naoxintong Capsule;
♦ Bach number: 200501.
Study drug 2: Buyang Huanwu Granule
♦ Ingredients: *Astragalus mongholicus* Bunge [Fabaceae; Radix Astragali], *Angelica sinensis* (Oliv.) Diels [Apiaceae; Angelicae Sinensis Radix], *Paeonia lactiflora* Pall. [Paeoniaceae; Paeoniae Radix Rubra], Lumbricus rubellus (*Oligochaeta*, Lumbricidae), *Ligusticum chuanxiong* Hort. [Apiaceae; Chuan xiong Rhizoma], *Carthamus tinctorius* L. [Asteraceae; Carthami Flos], *Prunus persica* (L.) Batsch [Rosaceae; Semen Persicae].
♦ Property: granule; the contents are brown to black brown granules; bitter in taste;
♦ Specification: 5.5g/ bag;
♦ Bach number: 200603.
Placebo 2: Granule placebo
♦ Ingredients: dextrin, 1% Ligusticum chuanxiong, bitterness SA, stevioside, lemon yellow, and chocolate brown;
♦ With identical color, specification, packaging, property of contents and other features with Buyang Huanwu granule;
♦ Bach number: 200601.

Table 2 Measurement items and time points for data collection.

Item	Run-in period	Baseline period	Intervention period
	(-14±1) day	(-7~0) days	(28 ± 4) days
Basic information			
Informed consent	×		
Inclusion/exclusion criteria		×	
Demographic data	×		
Randomization		×	
Record medical history and allergy history	×		
Record complication and symptom	×		
Record concomitant medication	×		
Access to the "Doctor Tao" platform	×		
Urine pregnancy test	×		
Safety assessment			
Vital signs and physical examination	×	×	×
Blood and urine routine examination		×	×
Liver function (ALT, AST, AP, TBIL, γ-GT)		×	×
Kidney function (SCr, BUN)		×	×
Coagulation function (PT, APTT, TT, FIB, INR)		×	×
Fasting blood glucose		×	×
Efficacy indicators			
Stable angina symptom score		×	×
Electrocardiogram		×	×
Seattle Angina Questionnaire		×	×
Nitroglycerin consumption	×	×	×
Other works			
Drug distribution	×	×	
Drug recycling		×	×

Record adverse events and combined medication	×	×
Compliance judgment	×	×

Note: ALT=alanine aminotransferase, AST=aspartate aminotransferase, AP=alkaline phosphatase, TBIL=total bilirubin, γ-GT=γ-glutamyl transpeptidase, SCr=serumcreatinine, BUN=blood urea nitrogen, PT=prothrombin time, APTT=actived partial thrombolastin time, TT=thrombin time, FIB=fibrinogen, INR=international normalized ratio.

Figures

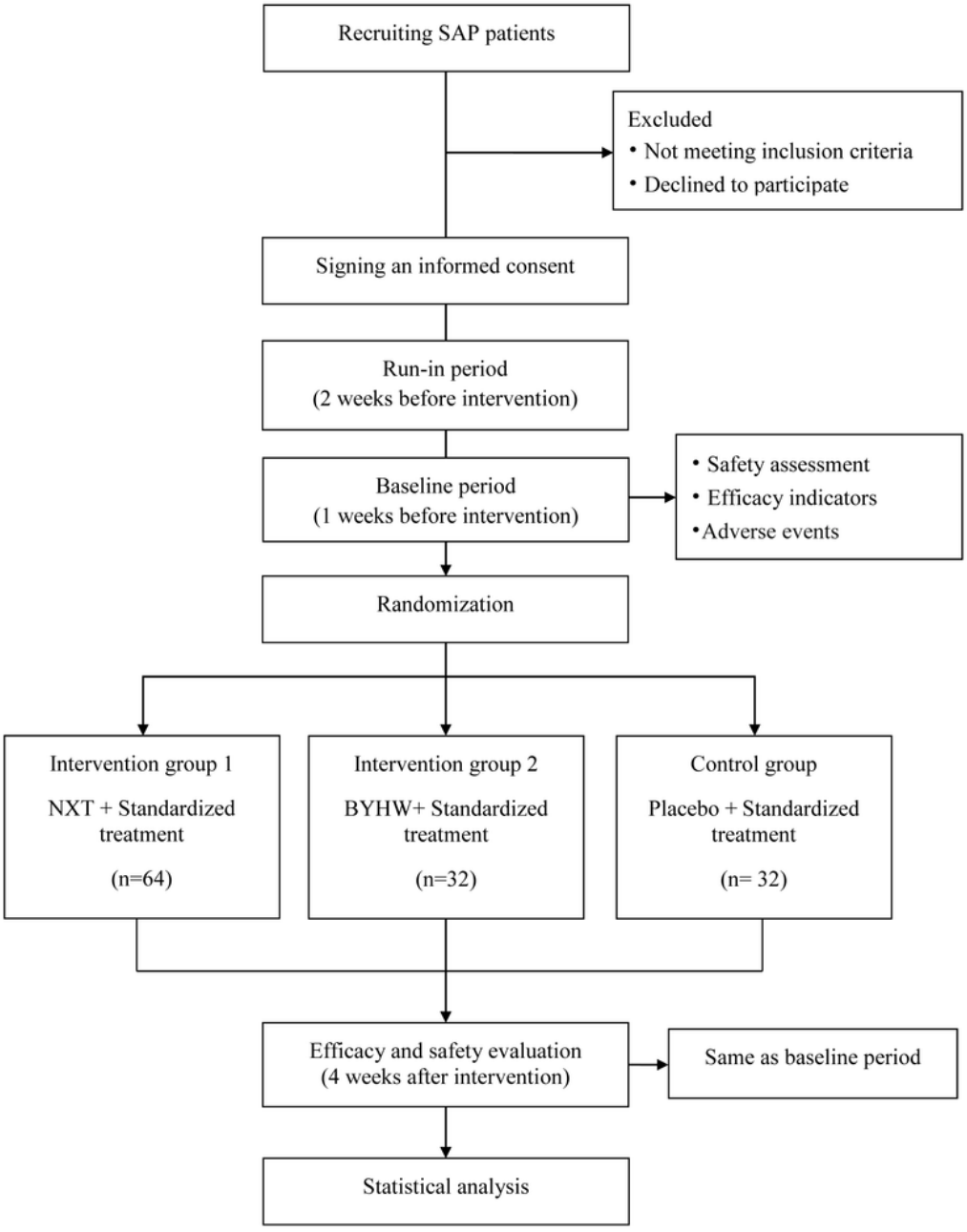

Figure 1

Study flowchart