

Original article

CORE-DITEC-BS (CONvergence REsearch of the Diagnostic TEchnology for Blood Stasis): Study protocol[☆]

Ju Ah Lee^{a,1}, Byoung-Kab Kang^{a,1}, Tae-Yong Park^b, Hoyoung Lee^a, Jong-In Kim^c,
Seong-Uk Park^c, Jinho Lee^d, Byung-Cheul Shin^e, Jung-Han Lee^f, Sung-Se Son^g, Dong-Il Kim^h,
Minho Cha^a, Kyung-Jin Yoon^a, Bongki Park^a, Sooseong You^a, Jeeyoun Jung^a, Mi Mi Ko^a,
Jiae Choi^a, Tae-Young Choi^a, Eun Hyoung Shim^a, Ji Hee Jun^a, Myeong Soo Lee^{a,*}

^a Medical Research Division, Korea Institute of Oriental Medicine, Daejeon, South Korea

^b Department of Integrative Medicine, Catholic Kwandong University, International St. Mary's Hospital, Incheon, South Korea

^c College of Korean Medicine, Kyung Hee University, Seoul, South Korea

^d Jaseng Spine and Joint Research Institute, Seoul, South Korea

^e School of Korean Medicine, Pusan National University, Yangsan, South Korea

^f Department of Korean Medicine, Wonkwang University, Iksan, South Korea

^g Department of Acupuncture & Moxibustion, CHA Bundang Medical Center, CHA University

^h College of Korean Medicine, Dongguk University, Ilsan, South Korea

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Abstract

Introduction: The blood stasis pattern in Chinese and Korean traditional Medicine is characterised by stagnation, including extravasated blood and sluggish blood circulation or viscous or congested blood, all of which may become pathogenic factors. Blood stasis is associated with chronic and incurable disease, such as pain, infertility, cancer and health reducing conditions caused by stress, which are not relieved with modern medicine. The aim of the study is to establish a modern concept of blood stasis, develop diagnostic tools and diagnostic indices for blood stasis, identify biological indices related to blood stasis.

Methods: This community-based, multi-centre trial is designed as an observational study. Data will be collected in order to standardise blood stasis diagnosis in Korea. Patients will be admitted to one of the following 7 hospitals participating in this study: Kyung Hee Oriental Medical Centre, Kyung Hee University Oriental Hospital at Gangdong, Wonkwang Oriental Medical Hospital, Jaseng Hospital of Oriental Medicine, Cha Medical Centre, Pusan National University Korean Medicine Hospital and Dongguk University Ilsan Oriental Hospital. A total of 1400 participants will be recruited through local advertising and doctor referrals from hospitals. At each site, 200–280 participants will be recruited.

Ethics and dissemination: All of the research aims, the study design, and the specific methods in this study have been approved by the Institutional Review Boards (IRB) of all seven of the participating hospitals. Additionally, the study was approved by the IRB of the Korean Institute of Oriental Medicine.

Trial registration: CRIS No. KCT 0000916

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Introduction

In Chinese medicine, blood stasis (BS) refers to the condition in which blood flow is slowed down or completely stopped [1]. The blood stasis pattern is characterised by stagnation, including extravasated blood and sluggish blood circulation or viscous or congested blood, all of which may become pathogenic [2].

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* Corresponding author. Tel.: +82 42 868 9266; fax: +82 42 868 9622.

E-mail addresses: drmslee@gmail.com, mslee@kiom.re.kr (M.S. Lee).

¹ Both authors contributed equally.

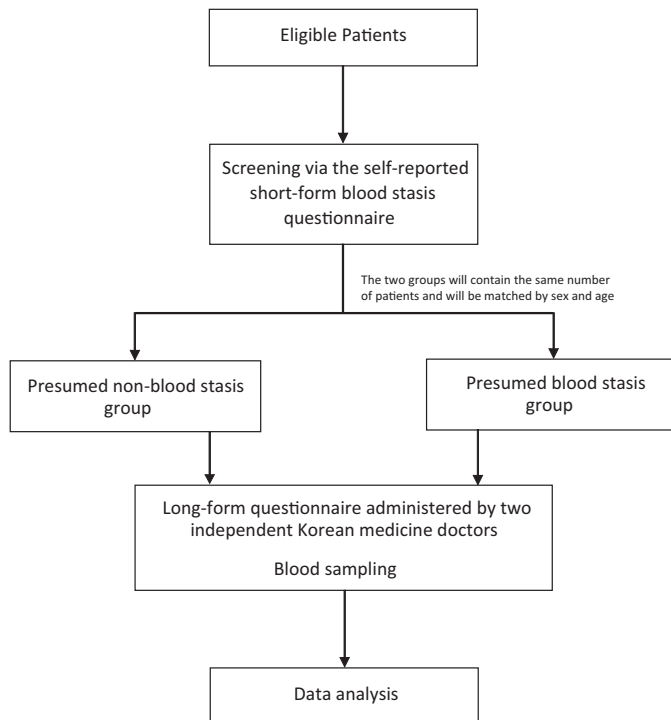


Fig. 1. Study procedure.

Blood stasis is associated with chronic and incurable diseases, such as pain, infertility, cancer, coronary heart disease and health reducing conditions caused by stress, which are not relieved with modern medicine [1].

Increasingly, the clinical evidence for Chinese medicine has demonstrated its effectiveness for several diseases [3–9]. Therefore, it is crucial to objectively standardise the diagnostic criteria for blood stasis using a scientific method. If a scientific and objective standard for the diagnosis and treatment of blood stasis could be established, it would facilitate the development of evidence-based medicine (EBM) for Korean traditional medicine. And it will be easier to both conduct more and better research with Korean traditional medicine and expand its benefits and utilization for the public.

In this study, we aim to establish the modern concept of blood stasis by developing a diagnostic tool and diagnostic indices for blood stasis, identify the biological indices related to blood stasis, construct a clinical study base and database for diagnosing and treating blood stasis, and establish traditional Korean medicine diagnoses and treatments for blood stasis diseases.

Methods and analysis

Study design

This study will be a community-based, multi-centre trial designed as a cross-sectional observational study (Fig. 1). The data will be collected as part of a multi-centre study for the standardisation of a blood stasis diagnosis in Korea. And we will conduct Standard Operation Procedures (SOP) training for every practitioners to unify diagnose process.

Table 1
Inclusion/exclusion criteria.

Inclusion criteria	
Males and females aged between 20 and 70 years	
Written informed consent to participate given	
Agreement to comply with regulations	
Agreement with the aim of this study and to blood sampling	
Exclusion criteria	
Patients with any psychiatric condition that leaves them unable to communicate	
Unconscious critical patients who are difficult to communicate with	
Pregnant women	
Patients with any conditions that might have an influence on assessment for this study	

Participants

A target sample of patients will be recruited from the following 7 traditional Korean medical hospitals: Kyung Hee Oriental Medical Centre, Kyung Hee University Oriental Hospital at Gangdong, Won Kwang Oriental Medical Hospital, Jaseng Hospital of Oriental Medicine, Cha Medical Centre, and Pusan National University Korean Medicine Hospital. A total of 1400 participants will be recruited through doctor referrals from the hospitals. At each site, between 200 and 280 participants will be recruited. The study will be conducted between July 2013 to December 2014. After year 1 and year 2, we will collect the patients who have diseases related BS. We expect to obtain information regarding the research during year 1 and year 2.

Inclusion and exclusion criteria

The participants who meet all of the following requirements will be eligible for enrolment (Table 1). The eligibility criteria will be as follows: males or females aged between 20 and 70 years who give their written informed consent to participate and agree to comply with the study regulations. The exclusion criteria are patients with any psychiatric condition that renders them unable to communicate; patients that are critically ill; pregnant women; or patients with any condition that could influence the study assessment.

Sample selection

The participants will be matched by sex, age and the presumption of blood stasis vs non-blood stasis. To determine the presumption of blood stasis/non-blood stasis the short-form questionnaire for blood stasis (Table 2) will be used, the participants will be divided into a blood stasis presumption group and

Table 2
The short-form questionnaire for blood stasis.

No.	Questionnaire items	Yes	No
1	Tends to bruise easily		
2	Nocturnal pain		
3	Haemorrhoids		
4	Dark colouration of the periorcular region		
5	Scaly and rough skin		
6	Dark facial complexion		
7	Sharp pain		
8	Menstrual pains (women only)		

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