Population pharmacokinetic modeling of Qishe pill in three major TCM-defined constitutional types of healthy Chinese subjects: Study protocol for a phase-I clinical trial

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Background: With the greatly increased morbidity of neck pain, it brought a large challenge to some optimal therapies for various situations in population at a given time based on their demographic, physiological and pathological characteristics. Based on the YQHYTL formula, Qishe Pill (Shanghai Sundise Traditional Chinese Medicine Co., Ltd, China) has been developed and spread in use into clinical settings in 2009. As individualization has become the trend of modern medicine, a personalized medicine of Qishe Pill should be documented and practiced with various patients according to the ancient TCM system, a classification of personalized constitution type, which has been established to determine predisposition and prognosis to diseases as well as therapy and life-style administration.

Objective: Therefore, we describe the population pharmacokinetic profile of Qishe Pill and compare its extent of metabolism in the 3 major constitution types (Qi-Deficiency, Yin-Deficiency and Blood-Stasis) to address major challenges of individualized and standardized Traditional Chinese Medicine into clinical practice.

Methods: Healthy subject cohorts (N=108) with an emphasis on constitutional types are being established following a standardized pharmacokinetic protocol for the assessment of demographic, physiological, pathological information, laboratory biomarkers, and the collection of blood samples for the PK analysis and second-generation gene sequencing. In the single-dose administration stage, subjects in each constitutional type cohort (N=36) will be randomly divided into three groups with three different doses of Qishe Pill (3.75, 7.5 and 15 grams) relatively.

Conclusion: Comparing with the general background population as characterized, a systematic population pharmacokinetic (Pop PK) model for Qishe Pill will be established and verified. Ethical research projects on informed consent procedures and reporting of incidental findings will be launched in parallel.

Biography
Yue-Li Sun is a PhD candidate at Shanghai University of TCM. He has conducted two large-sized multi-center RCTs (Phase II & Phase IV) in China, two cohorts about cervical spondylotic myelopathy (CSM) and adolescent idiopathic scoliosis (AIS) in Shanghai and a population pharmacokinetics in his Master’s career. After turning towards the mechanism, he is focused on the molecular and cellular biological research about fluid mechanics and population pharmacokinetics research. He has published more than 15 papers in reputed journals.

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