

Chinese Herbal Formula Xuefu Zhuyu for Qi-stagnation and Blood-stasis Pattern: Rationale and Design of a Master Protocol Study for Post-marketing Evaluation

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The notion of “treating different diseases with the same method” refers to treating different diseases belonging to a certain Chinese medicine (CM) pattern (zheng in Chinese). Proprietary Chinese medicines (PCMs) are usually applied for multiple diseases with the same CM pattern. However, this notion is rarely used for the post-marketing effectiveness evaluation of PCM. Here, we present the rationale and design of a master protocol study to clarify the effectiveness and safety of PCM on a CM pattern in order to explore a research paradigm for PCM effectiveness evaluation. The master protocol will be followed to conduct three registry-based cohorts where patients diagnosed with stable angina (SA), tension-type headache (TTH) or primary dysmenorrhea (PD) will be screened for participation, and three double-blinded randomized controlled trials (RCTs) investigate Xuefu Zhuyu (XFZY) oral liquid for those patients with qi-stagnation and blood-stasis pattern (QBP). Each RCT is accompanied with a real-world observational study, in which patients diagnosed as non-QBP will be enrolled. This study will totally enroll 1414 patients. In RCTs (574), participants will receive either XFZY oral liquid or placebo, while in observational studies (840), the medication will be prescribed according to the specific condition. The primary outcome is the visual analog scale (VAS) of pain intensity and the secondary outcomes are also related to characteristics of diseases. Adverse events will be reported. Different statistical analysis methods are adopted. The master protocol study is highly consistent with the flexibility of treatment based on Chinese pattern differentiation, which enriches CM effectiveness evaluation methods.

Biography

Wencong Cao is a doctoral student in Guangzhou University of Chinese Medicine, majoring in the clinic epidemiology. She has been focusing on clinical research related to traditional Chinese medicine, especially making an effort to the design, measurement and evaluation of the real world study. She has published more than 5 papers in reputed journals as the first author.