

## Chinese Herbal Formula Huoxiang Zhengqi for Dampness Pattern in Atopic Dermatitis and Diarrhea-predominant Irritable Bowel Syndrome: Rationale and Design of a Master Protocol

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Atopic dermatitis (AD) and diarrhea-predominant irritable bowel syndrome (IBS-D) are two recurrent diseases with limited effective treatments. In Chinese Medicine (CM) theory, they may share dampness pattern as the same dominant pathogenesis at a certain stage, thus can be treated with the same method. While Chinese herbal formula Huoxiang Zhengqi (HXZQ) has been reported as an effective dampness-resolving therapy for both AD and IBS-D, further high-quality clinical studies are still needed. In addition, HXZQ lacks of accurate clinical positioning based on CM patterns. Therefore, we utilize a master protocol design to evaluate HXZQ for dampness pattern simultaneously in AD and IBS-D, with the aim of identifying the pattern-defined population of HXZQ. This master protocol includes two randomized controlled trial (RCTs) and a real-world observational study. Based on two registry cohorts of AD and IBS-D, patients with dampness pattern will be enrolled in the RCTs to receive either HXZQ oral liquid or a placebo for 4 weeks and then be followed for another 4 weeks, while patients with non-dampness pattern will constitute the observational study and experience a 12 weeks of follow-up. A total of 678 AD patients and 322 IBS-D patients will be recruited from 14 hospitals in China over a 3-year period. The Eczema Area and Severity Index (EASI) and the proportion of responders for adequate relief (AR) are the primary outcome in AD and IBS-D respectively. Analysis will be undertaken separately in each substudy, then an overall analysis combining multiple subgroups will be performed to comprehensively investigate the effect of HXZQ.

### Biography

Qian Huang is studying for a doctorate in Chinese medicine at Guangzhou University of Chinese Medicine. Her main focus is on clinical research methods of Traditional Chinese Medicine. She has published several papers in reputed journals.