



### S4 – Chinese Herbal Medicine (MaZiRenWan) for Functional Constipation: A Prospective, Double-blinded, Double-dummy, Randomized, Controlled Study

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**Introduction and Project Objectives:** Functional constipation (FC) is a common clinical complaint. Despite the effectiveness of MaZiRenWan (MZRW) for alleviating functional constipation symptoms has been proved in our previous randomized placebo-controlled study, further evidence is needed to make clinical recommendations about Chinese herbal medicine, especially comparing with conventional western medicine for FC patients. The objective of this study is to evaluate the efficacy of MZRW by comparing with the first-line remedy, Senokot, for FC patients diagnosed with Excessive Pattern in traditional Chinese medicine (TCM). Transparent reporting of study details was made by following the extension of Consolidated Standards of Reporting Trials (CONSORT) for Chinese herbal medicine formulas.

**Methods:** This was a three-arm, randomized, controlled multicenter trials. 291 FC patients with Excessive Pattern were recruited. The interventions included MZRW with placebo Senokot, Senokot with placebo MZRW or double placebo with 8-week treatment and 8-week follow-up respectively. The primary outcome was the responder rate for complete spontaneous bowel movement (CSBM) during treatment, and secondary outcomes were colonic transit measured by radio-opaque markers, CSBM during follow-up period, individual and global symptom assessment, and reported adverse events.

**Results:** Of 843 candidates, 291 eligible patients were randomly assigned to MZRW group (n=97), Senokot group (n=97) and placebo group (n=97). In total, 33 patients withdrew from the study. Responder rates for MZRW, Senokot and placebo groups were 68%, 57.7% and 33.0% during treatment, and 47.4%, 20.6% and 17.5% in the follow-up, respectively (P<0.005). The colonic transit significantly improved only in MZRW group after 8-week treatment. There was no severe adverse event during the treatment and follow-up.

**Conclusions:** MZRW is safe and effective for alleviating FC patients in Excessive Pattern by comparing with Senokot and placebo. Sustained benefits of MZRW are also shown in the follow-up period. Therefore, MZRW can be an alternative remedy for FC in clinical practice.

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