

Effectiveness and safety of Hongjin Xiaojie Capsule versus waiting list for breast pain

ABSTRACT

Background: Moderate to severe breast pain severely affects the quality of life for patients. Patent Chinese medicines are widely used in the treatment of breast pain due to their stable dosage form and precise efficacy.

Objective: To evaluate the beneficial effects and safety of Hongjinxiaojie capsule (HJXJC) in the treatment of cyclical breast pain.

Design, setting, participants and intervention: This is a multicenter, single-blind randomized controlled trial conducted in 3 medical centers in China from 2019 to 2021. Through center-stratified block group randomization, 298 women with moderate to severe cyclic breast pain were divided into the intervention group (n=150, treated with the HJXJC, four capsules per meal, thrice a day, during the 12 weeks) and the control group (n=148, waiting for treatment).

Main outcome measures: The main outcomes were breast pain score, pain duration, which were measured by Short-form McGill Pain Questionnaire (SF-MPQ) and patients' records at baseline, after weeks 4, 8, 12, and 16.

Results: The full analysis set (FAS) population was 298 and the per-protocol analysis set (PPS) population was 274. In the intervention group, The SF-MPQ scores were significantly lower than the control group at 12weeks (FAS: mean difference -12.55, 95%CI -13.90to-11.21, $p<0.01$;PPS: mean difference -13.07, 95%CI -14.48to-11.66, $p<0.01$). Duration of pain was significantly shorter in the intervention group(FAS:

mean difference -6.69, 95%CI -7.58to-5.80, $p < 0.01$ vs. control; PPS: mean difference -7.09, 95%CI -8.01to-6.16, $p < 0.01$ vs. control). The above indicators remained statistically significantly different between the two groups of patients at week 16. Moreover, no serious adverse events occurred in both groups, and there were no differences in safety variables.

Conclusions: HJXJC can significantly relieve breast pain, reduce its duration, reduce the size of breast lumps and relieve menstrual pain. However, it has no significant effect on breast nodules and uterine fibroid size.

Keywords: Hongjinxiaojie capsule, Cyclical breast pain, Randomized controlled trial, Traditional Chinese medicine