

14. Genitourinary Tract Disorders (including Climacteric Disorders)

Reference

Jang JB, Yoon YJ, Park JH, et al. Therapeutic effects of chiljehyangbuhwan on primary dysmenorrhea: A randomized, double blind, placebo-controlled study. *Complementary Therapies in Medicine* 2009; 17; 123–30.

1. Objectives

To evaluate the efficacy of Chiljehyangbuhwan (七製香附丸) on primary dysmenorrhea.

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

One Oriental hospital (Kyunghee University Medical Center), Republic of Korea.

4. Participants

Patients (age, 14–45 years) with active menstrual pain (not due to secondary dysmenorrhea, not related to conditions causing pelvic pain outside the uterus, and not related to drug interactions) (n=100).

5. Intervention

Arm 1: Chiljehyangbuhwan (七製香附丸) treatment, 3 times a day, 30 minutes after meals, for one menstrual cycle.

Arm 2: Placebo drug treatment, 3 times a day, 30 minutes after meals, for one menstrual cycle.

After eliminating 29 subjects who were lost to follow up and/or who showed adverse drug reactions, a total of 71 subjects (34 in the Chiljehyangbuhwan group and 37 in the placebo group) completed the study.

6. Main Outcome Measures

Menstrual pain severity evaluated on a unidimensional scales (visual analogue scale [VAS] and verbal rating scale [VRS]) and multidimensional scales (multi-dimensional VRS [MVRS]).

7. Main Results

Treatment significantly decreased pain (decreased VAS, VRS, and MVRS scores) in both arms, but the decrease was significantly greater in Arm 1. Neither treatment affected the results of blood analysis, hepatic and kidney function tests.

8. Conclusions

Chiljehyangbuhwan significantly decreases pain due to dysmenorrhea.

9. Safety assessment in the article

The safety of the Chiljehyangbuhwan preparation was evaluated on the basis of liver function tests, urine analysis, complete blood counts, and pelvic ultrasound. All tests were normal. Adverse reactions were recorded on observation charts, and while 8 in the Chiljehyangbuhwan group reported various forms of discomfort, most symptoms were mild and subsided within 2–3 days and none of the subjects chose to withdraw from the trial for these reasons. The 2 subjects who eventually withdrew were all from the placebo group. Therefore, the Chiljehyangbuhwan preparation showed sufficient clinical safety.

10. Abstractor's comments

In this study, the final analysis included only a small number of patients as many patients dropped out during the trial. Moreover, analysis of efficacy and safety was limited by the small number of patients, drug taking, and short observation period. As the symptoms of dysmenorrhea persist over multiple menstrual cycles, extension of treatment and the observation period as well as methods to minimize the drop-out rate should be considered. Moreover, objective rather than subjective methods for evaluating dysmenorrhea should be used and are needed.

11. Abstractor and date

Cho JH, 16 July 2010.