

**2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)****Reference**

Jeong JS, Ryu BH, Kim JS, et al. Bojungikki-tang for cancer-related fatigue: A pilot randomized clinical trial. *Integrative Cancer Therapies* 2010; 9: 331–8. CENTRAL ID: CN-00770648, Pubmed ID: 21059621

**1. Objectives**

To evaluate the effectiveness of hochuekkito (補中益氣湯) for cancer-related fatigue.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

East-West Neo Medical Center, Kyung Hee University, Republic of Korea.

**4. Participants**

Forty patients with cancer-related fatigue (May to October 2009).

**5. Intervention**

Arm 1: TSUMURA Hochuekkito (補中益氣湯) Extract Granules 7.5 g/day for 2 weeks (n=20).

Arm 2: no treatment, course monitored for 2 weeks (n=20).

**6. Main outcome measures**

Primary outcome measure: Visual Analogue Scale of Global Fatigue (VAS-F)

Secondary outcome measures: Functional Assessment of Cancer Therapy-General (FACT-G), Functional Assessment of Cancer Therapy-Fatigue (FACT-F), Trial Outcome Index-Fatigue (TOI-F).

**7. Main results**

Eighteen patients were included in each group for evaluation. Significant improvements were observed in arm 1 compared to arm 2 for before/after changes in all measures, VAS-F ( $P=0.040$ ), FACT-G ( $P=0.047$ ), FACT-F ( $P=0.025$ ), and TOI-F ( $P=0.049$ ).

**8. Conclusions**

Hochuekkito improves cancer-related fatigue.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Blood tests (aspartate amino transferase [AST], alanine aminotransferase [ALT], creatinine, blood urea nitrogen [BUN]) were performed before and after administration, and participants were asked about subjective symptoms using a questionnaire based on version 2.0 of the NCI-CTC-AE questionnaire. Although these results showed no significant change in liver or kidney function, two participants complained of grade 1 stomach discomfort.

**11. Abstractor's comments**

While fatigue is the most commonly known indication for hochuekkito, this study is valuable for having verified its effectiveness and safety for cancer patients through an RCT. Yet, the inclusion criteria included a two-month gap since chemo- or radiotherapy, which raises questions about whether their influence could really be ruled out. Furthermore, a placebo effect cannot be completely ruled out because no treatment was administered in arm 2, and the administration period was only two weeks. In future, such a study would hopefully give the control group a placebo, or increase the number of subjects, for treatment over a longer period.

**12. Abstractor and date**

Motoo Y, 31 December 2012.