

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

Kato S, Kishiro I, Machida S, et al. Combined effects of hochu-ekki-to (*bu-zhong-yi-qi-tang*) and clarithromycin on Lung Carcinoma. *Kampo to Meneki-Arerugi (Kampo and Immuno-Allergy)* 1999; 13: 83-8 (in Japanese with English abstract).

**1. Objectives**

To evaluate the efficacy of hochuekkito (補中益氣湯) combined with clarithromycin (CAM) for improvement in the prognosis of lung cancer.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

A university hospital (Department of Internal Medicine, Dokkyo Medical University Hospital), Japan.

**4. Participants**

Thirty-five patients with primary lung cancer lesions that responded to chemotherapy or radiotherapy either partially or completely (21 males, 14 females; mean age, 63.2±6.7 years; performance status [P.S.] 0-2; baseline clinical stage Ia [n=5], Ib [n=21], and II [n=9]; squamous cell carcinoma [n=14], adenocarcinoma [n=21]).

**5. Intervention**

Arm 1: combination therapy group; 400 mg/day of CAM + 7.5 g/day of hochuekkito (補中益氣湯) extract granules administered to 17 patients (10 males, 7 females; mean size reduction of the primary lesion, 62.8 ± 11.2%).

Arm 2: monotherapy group; 400 mg/day of CAM administered to 18 patients (11 males, 7 females; mean size reduction of the primary lesion, 66.7±8.6%).

**6. Main outcome measures**

Tumor markers, NK cell activity (at baseline, and 2 and 12 months after the start of treatment), and 1-year survival.

**7. Main results**

Serum levels of tumor markers were significantly elevated in both treatment groups compared with the control group. In patients surviving 1 year after the start of treatment, NK cell activity, representing immunoreactivity, was elevated in both treatment groups, and was significantly higher in the combination therapy group than the control group.

**8. Conclusions**

The combination (hochuekkito plus CAM) seems to be effective for maintaining the efficacy of chemotherapy and radiotherapy.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

None.

**11. Abstractor's comments**

This study deserves praise for attempting to conduct RCT targeting a difficult-to-treat pathology of lung cancer prognosis. Regrettably, however, it is unclear whether "the control group" mentioned here refers to the CAM monotherapy group or yet another group, or to a before-after comparison in the same group. Clarification of the study is expected.

**12. Abstractor and date**

Tsuruoka K, 15 June 2007, 1 April 2008, 1 June 2010.