

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

Mori K, Saito Y, Tominaga K. Utility of hochu-ekki-to in general malaise accompanying lung cancer chemotherapy. *Biotherapy* 1992; 6: 624–7 (in Japanese with English abstract). Ichushi Web ID: 1993020654

1. Objectives

To evaluate the efficacy of hochuekkito (補中益気湯) for the prevention and relief of general malaise related to chemotherapy for primary lung cancer (squamous cell carcinoma, adenocarcinoma, and small cell carcinoma).

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital, Japan.

4. Participants

Forty-one patients with stage III–IV lung cancer receiving (cisplatin 25 mg/m² for 5 days) + (vindesine 3 mg/m² at days 1 and 8 or etoposide 100 mg/m² at days 1, 3, and 5) every 3 or 4 weeks.

5. Intervention

A table of random numbers was used for group assignment.

Arm 1: TSUMURA Hochuekkito (補中益気湯) Extract Granules 7.5 g/day (beginning from 7 or more days before the start of anticancer drug treatment) (n=21).

Arm 2: no administration of hochuekkito (補中益気湯) (n=20).

6. Main outcome measures

Subjective symptoms (general malaise, mood, appetite, and nausea/vomiting) after 1–4 cycles of chemotherapy in arm 1 or 2–4 cycles in arm 2, recorded in a health diary for comparison.

7. Main results

General malaise, mood, and appetite were significantly improved in arm 1 ($P < 0.01$), but there was no significant between-arm difference in the severity of nausea/vomiting.

8. Conclusions

Hochuekkito is useful for prevention of general malaise and improvement of mood and appetite in patients on chemotherapy (including cisplatin) for primary lung cancer.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

There were no adverse drug reactions in arm 1, and none was mentioned in arm 2.

11. Abstractor's comments

The authors concluded that hochuekkito combined with anticancer drugs (cisplatin + α) is useful for prevention of general malaise and improvement of mood and appetite. Symptoms were graded ensuring objectivity to some degree, although the study was not blinded. However, improvement was not rated at the same time point in arm 1 (after 1–4 cycles) and arm 2 (after 2–4 cycles). Improvement should have been evaluated over time in both arms after a fixed number of chemotherapy cycles.

12. Abstractor and date

Hoshino E, 6 May 2009, 31 December 2013.