

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

Sugimachi K. A study of the usefulness of ninjin'yoeito in the postoperative adjuvant chemotherapy for gastric cancer\*. *Rinsho to Kenkyu (Japanese Journal of Clinical and Experimental Medicine)* 1995; 72: 454–8 (in Japanese). Ichushi Web ID: 1995168756 [MOL, MOL-Lib](#)

**1. Objectives**

To evaluate the efficacy of ninjin'yoeito (人參養榮湯) for reducing adverse effects and improving performance status (PS) in patients undergoing postoperative adjuvant chemotherapy (fluoropyrimidine anticancer drug) for gastric cancer.

**2. Design**

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

**3. Setting**

Three university hospitals (2nd Department of Surgery, Kyushu University, 2nd Department of Surgery, Fukuoka University, 2nd Department of Surgery, University of Occupational and Environmental Health) and 19 other hospitals, Japan.

**4. Participants**

Forty-six postoperative patients with stage I-IV gastric cancer undergoing gross curative resection.

**5. Intervention**

Arm 1: fluoropyrimidine anticancer drug + KANEBO Ninjin'yoeito (人參養榮湯) Extract Granules 2.5 g t.i.d. from 2 to 14 weeks postoperatively (n=27).

Arm 2: fluoropyrimidine anticancer drug alone (n=19).

**6. Main outcome measures**

Hematological measures (white blood cell [WBC], red blood cell [RBC], and platelet counts), body weight, PS, subjective symptoms (appetite, nausea/vomiting, and diarrhea) at 14 weeks after the start of administration.

**7. Main results**

Change in body weight, PS: no significant difference between arms.

Decrease in RBC count, platelet count: a smaller decrease in arm 1, although not significantly smaller.

Decrease in WBC count: no significant between-arm difference.

Degree of improvement in subjective symptoms: no significant between-arm difference.

**8. Conclusions**

Ninjin'yoeito (人參養榮湯) tends to suppress the decreases in RBC count and platelet count but not the decrease in WBC count and does not improve PS in patients undergoing postoperative adjuvant fluoropyrimidine-based chemotherapy for gastric cancer.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Adverse drug reactions in arm 1 did not occur, and adverse events in arm 2 were not mentioned.

**11. Abstractor's comments**

The authors concluded that ninjin'yoeito combined with the anticancer drug (fluoropyrimidine) has therapeutic usefulness. However, given that the physicians were not blinded to the patient's clinical information and medical status, the finding that the intervention was effective may have been biased. It is problematic that the extent of intraoperative progression and invasion varied between patients and that patients were included who had early-stage and advanced gastric cancer; differentiated and undifferentiated gastric cancer; partial, subtotal, and total gastrectomy; and stage I to IV disease. The fluoropyrimidine drugs also varied. Comparison should have been made between groups of patients with homogeneous baseline characteristics. Such heterogeneity may have contributed to the failure to show a significant improvement in subjective symptoms. Use of a protocol designed to optimally rather than uniformly administer ninjin'yoeito or to select the optimal Kampo medicine [*hozai* (補劑, formulations with tonic effects)] (i.e., hochuekkito, juzentaihoto, or ninjin'yoeito) would have resulted in a significant difference.

**12. Abstractor and date**

Hoshino E, 15 February 2009, 1 June 2010.