

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

Yamamoto T, Fujita H, Okada H, et al. Clinical evaluation of the effects of ninjin'yoeito on subjective and objective symptoms and bone-marrow function during chemotherapy or radiotherapy in female patients with genital cancer. *Oncology & Chemotherapy* 1994; 10: 126–34.

**1. Objectives**

To evaluate the efficacy of ninjin'yoeito (人參養榮湯) against subjective and objective symptoms and myelosuppression due to postoperative chemotherapy or radiotherapy in female patients with genital cancer.

**2. Design**

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

**3. Setting**

Department of Obstetrics and Gynecology, Kyoto Prefectural University of Medicine, and 8 related facilities, Japan.

**4. Participants**

Forty patients undergoing cancer chemotherapy or radiotherapy (excluding those with serious complications or Eastern Co-operative Oncology Group (ECOG) performance status (PS) 4 at entry, or those judged by the investigator to be ineligible).

**5. Intervention**

Arm 1: chemotherapy + Kanebo (currently Kracie) Ninjin'yoeito (人參養榮湯) Extract Fine Granules 2.5 g t.i.d (n=11).

Arm 2: chemotherapy + cepharanthine 2 tablets t.i.d. (n=12).

Arm 3: radiotherapy + Kanebo (currently Kracie) Ninjin'yoeito (人參養榮湯) Extract Fine Granules 2.5 g t.i.d (n=10).

Arm 4: radiotherapy + cepharanthine 2 tablets t.i.d. (n=7).

Duration of administration: at least 2 weeks (more than 4 weeks if possible)

**6. Main outcome measures**

Four performance status items evaluated on a 5-point scale, nausea/vomiting evaluated on a 4-point scale, hematology (blood counts, biochemistry), and urinalysis (protein, glucose, and urobilinogen).

**7. Main results**

Kampo medicine treatment significantly improved myelosuppressive symptoms but not subjective and objective symptoms associated with anticancer drug administration. It also improved anorexia and fatigue/malaise during radiotherapy.

**8. Conclusions**

Ninjin'yoeito is effective for reducing myelosuppression associated with anticancer drug administration and radiotherapy.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

One patient had acute hepatitis with unknown causal relationship to ninjin'yoeito.

**11. Abstractor's comments**

This study investigated the possible efficacy of ninjin'yoeito for relieving myelosuppression caused by anticancer drugs. Ninjin'yoeito improved anticancer drug-caused myelosuppression but not severe anorexia, consistent with other papers. A future report on its efficacy in patients treated with three or more cycles of chemotherapy is also awaited.

**12. Abstractor and date**

Nakata H, 1 January 2009 1 June 2010.