

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

Hasegawa K, Fukunishi H, Kiyoshige K, et al. Clinical usefulness of Kampo medicines (ninjin-yoei-to, juzen-taiho-to) for side effects in gynecologic cancer chemotherapy – Effects on reducing side effects by CDDP in CAP therapy–. *Wakan Iyakugaku Zasshi (Journal of Traditional Medicines)* 1994; 11: 181–7 (in Japanese with English abstract).

**1. Objectives**

To evaluate the efficacy of combination of ninjin'yoeito (人參養榮湯) and juzentaihoto (十全大補湯) for reducing adverse effects of cyclophosphamide, adriamycin, cisplatin (CAP) chemotherapy including myelosuppression, renal impairment, and gastrointestinal symptoms.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

Department of Obstetrics and Gynecology, Hyogo Medical Center for Adults, Department of Obstetrics and Gynecology, Kobe National Hospital (currently National Hospital Organization Kobe Medical Center), Department of Obstetrics and Gynecology, Kobe City Medical Center West Hospital, and another 4 facilities, Japan.

**4. Participants**

Thirty-two patients with ovarian, uterine cervical, or uterine corpus cancer undergoing CAP therapy.

**5. Intervention**

Arm 1: oral administration of Kanebo (currently Kracie) Ninjin'yoeito (人參養榮湯) Extract Fine Granules 2.5 g t.i.d and Juzentaihoto (十全大補湯) Extract Granules 2.5 g t.i.d. for 5 weeks from 1 week before to 4 weeks after administration of anticancer drugs (n=19).

Arm 2: no administration (n=13).

**6. Main outcome measures**

Pre- and post-treatment myelosuppression and nephrotoxicity evaluated by hematology (blood counts, urea nitrogen, serum creatinine), and subjective symptoms (general malaise, anorexia, and vomiting) evaluated on a 4-point scale using a standard questionnaire.

**7. Main results**

Kampo medicine treatment did not significantly affect decreases in white blood cell (WBC), red blood cell (RBC), and platelet counts but tended to promote their reversal. Kampo medicine also reduced nephrotoxicity (i.e., normalized blood urea nitrogen [BUN] level and reduced creatinine fluctuation). Subjective gastrointestinal symptoms were not improved.

**8. Conclusions**

The combination of ninjin'yoeito and juzentaihoto is effective for reducing myelosuppression and nephrotoxicity associated with anticancer drug administration.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

There were no adverse drug reactions worth special mention.

**11. Abstractor's comments**

This study investigated the possible efficacy of combination of ninjin'yoeito and juzentaihoto for relieving myelosuppression and nephrotoxicity, which are important factors affecting completion of anticancer drug treatment. Further investigation is expected. While reduction in subjective symptoms by ninjin'yoeito has been reported, the present study did not demonstrate such an effect. This may be attributable to the increased amount of jio and toki resulting from the combination of ninjin'yoeito with juzentaihoto, given that one-third of patients failed to take the full dose of 7.5 g. It would be interesting to investigate this point in the future.

**12. Abstractor and date**

Nakata H, 1 January 2009, 1 June 2010.