

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

Mizuno M, Yoshikawa H, Taketani Y, et al. Clinical effects of ninjin'yoeito on performance status (PS) and recovery of physical strength in patients following gynecologic cancer treatment – comparison with no-treatment controls–. *Sanka to Fujinka (Obstetrics and Gynecology)* 1993; 60: 1533–45 (in Japanese). Ichushi Web ID: 1994139265 [MOL](#), [MOL-Lib](#)

1. Objectives

To evaluate the efficacy of ninjin'yoeito (人參養榮湯) for relieving subjective symptoms and improving activities of daily living in patients following gynecologic cancer surgery.

2. Design

Randomized controlled trial (RCT).

3. Setting

University of Tokyo Hospital, National Hospital Organization Medical Center, and 21 other facilities, Japan.

4. Participants

Inclusion criteria: gynecologic cancer (uterine cervical, uterine corpus, ovarian, etc.); more than 1 month since the completion of the initial treatment or treatment for recurrence; outpatient with at least one of the following subjective symptoms: anorexia, fatigue/malaise, decreased physical strength, cold limbs, night sweats, and lightheadedness; age, 15–75 years; Eastern Cooperative Oncology Group (ECOG) performance status (P.S.) ≤2; and no recurrence of cancer.

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. for 12 weeks (n=46).

Arm 2: no administration for 12 weeks (n=44).

6. Main outcome measures

Improvement in subjective symptom scores was used to measure efficacy.

7. Main results

Ten patients were excluded. Global improvement rating was significantly higher in arm 1. Stratified analysis revealed no significant between-arm difference for patients only receiving surgery, and significantly higher efficacy in arm 1 for patients also receiving chemotherapy and radiotherapy.

8. Conclusions

Ninjin'yoeito is expected to be useful for relieving subjective symptoms such as fatigue/malaise and regaining ability to perform activities of daily living following gynecologic cancer surgery.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

None.

11. Abstractor's comments

This study evaluated the efficacy of ninjin'yoeito for relieving subjective symptoms and improving activities of daily living after surgery to remove a gynecologic cancer. Considering that patients can be expected to value a therapy that relieves subjective symptoms such as fatigue/malaise and restores their ability to perform activities of daily living following gynecologic cancer surgery, a study report like this one is very meaningful. It would be interesting to investigate prognosis.

12. Abstractor and date

Nakata H, 1 January 2009, 1 June 2010.