

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

Oda T. My prescription – clinical application of ninjin'yoeito during chemotherapy for gynecologic cancer: the preventive effect on bone marrow suppression*. *WE* 2004; 9: 5-6 (in Japanese). Ichushi Web ID: 2006050757

Oda T, Ohnuki T, Kihara K, et al. A clinical study of a traditional Chinese herbal medicine, ninjin-yoei-to in bone marrow suppression due to chemotherapy in gynecologic cancer. *Yamagata Kenritsu Byoin Igaku Zasshi (The Yamagata Journal of Medicine)* 2004; 38; 6-9 (in Japanese). Ichushi Web ID: 2004222295

1. Objectives

To evaluate the efficacy of ninjin'yoeito (人參養榮湯) for reducing myelosuppression due to chemotherapy for gynecologic cancer.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

One hospital, Japan.

4. Participants

Eight patients who underwent surgery for gynecologic cancer (ovarian [n=6], uterine [n=1], or fallopian tube [n=1] cancer) and received granulocyte colony-stimulating factor (G-CSF) for neutropenia during the first cycle of chemotherapy (CAP: cyclophosphamide, Farmorubicin [epirubicin], cisplatin).

5. Intervention

Arm 1: treatment with Kanebo Ninjin'yoeito (人參養榮湯) Extract Fine Granules (7.5 g/day in two divided doses) continuously from 1 to 2 weeks prior to the start of the second cycle of chemotherapy (n=4).

Arm 2: no treatment with ninjin'yoeito (n=4).

6. Main outcome measures

The following measures during the second and third cycles of chemotherapy: nadir leukocyte and neutrophil counts, the length of time for neutrophil count to fall below 1,000/ μ L, total dose of G-CSF, duration of neutrophil counts under 1,000/ μ L, and nadir hemoglobin level and platelet count.

7. Main results

There were no significant between-arm differences in nadir leukocyte, neutrophil, and platelet counts or in the length of time for the neutrophil count to fall below 1,000/ μ L. Duration of neutrophil count under 1,000/ μ L tended to be shorter in arm 1 than in arm 2 during the second cycle, and became significantly shorter during the third cycle. Total dose of G-CSF tended to be lower in arm 1 than in arm 2 during the second cycle, and became significantly lower during the third cycle. Nadir hemoglobin level during the second cycle, compared with that during the first cycle, was significantly lower in arm 1, but not in arm 2.

8. Conclusions

It is strongly suggested that Kanebo Ninjin'yoeito Extract Fine Granules may exert neutropenia-preventing effects by inducing pluripotent stem cells to multiply and differentiate and by increasing the activity of G-CSF.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

None.

11. Abstractor's comments

Because of the small sample size (only four in each arm), it seems difficult to address the statistical significance of differences observed in this study. Furthermore, although G-CSF administration affects "total dose of G-CSF" and "duration of neutrophil counts under 1,000/ μ L," administration criteria for G-CSF are not described. Thus the data are not objective. The significant decrease in hemoglobin level in arm 1 may indicate that Kanebo Ninjin'yoeito Extract Fine Granules is effective against neutrophil suppression, but not against suppression of erythropoietic cells. It is necessary to include more patients and to investigate not only the efficacy, but also the adverse events induced by G-CSF.

12. Abstractor and date

Hoshino E, 15 March 2009, 1 June 2010.