

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

Takanami I, Ohnishi H. Clinical effects of ninjin-yoei-to as the immunopotentiator. *Kiso to Rinsho (The Clinical Report)* 1988;22: 1835-46 (in Japanese). Ichushi Web ID: 1989107413 [MOL](#), [MOL-Lib](#)

1. Objectives

To evaluate effects of ninjin'yoeito (人參養榮湯) prophylaxis dosing on the postoperative immune status in breast cancer patients.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital, Japan.

4. Participants

Thirteen patients with stage I or II breast cancer, aged ≤60 years.

5. Intervention

Arm 1: KANEBO Ninjin'yoeito (人參養榮湯) Extract Fine Granules 6.0 g/day (dosing frequency not stated), started 7 days before surgery and continued at the same dose up to approximately 4 weeks after surgery, excluding the day of surgery (n=7).

Arm 2: Control (no administration of ninjin'yoeito) (n=6).

6. Main outcome measures

Immunological parameters of peripheral white blood cell count, lymphocyte count, levels of OKT₃, OKT₄, OKT₈, OKIa₁, Leu 7, and Leu 11 antibodies, NK cell activity, and phytohaemagglutinin (PHA)-induced lymphocyte blastogenesis at 1 week before surgery as well as 1 day and 1, 2, 3, and 4 weeks after surgery.

7. Main results

At 4 weeks after surgery, the OKT₃ (pan T cell antibody) level was significantly higher in the ninjin'yoeito group (Arm 1) than in the control group (Arm 2) ($P<0.05$). Other endpoints showed no significant differences between the two groups.

8. Conclusions

Ninjin'yoeito has no apparent immunopotentiating effect in patients with stage I or II breast cancer.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not stated.

11. Abstractor's comments

Indications for ninjin'yoeito include "decreased physical strength after illness." This RCT evaluated ninjin'yoeito based on postoperative immune recovery in patients with stage I or II breast cancer. Among the immunological parameters examined, only OKT₃ showed significantly higher levels in the ninjin'yoeito group than in the control group. No other parameters showed significant differences between the groups. The authors reasonably concluded that ninjin'yoeito had no apparent immunopotentiating effect. However, the authors also stated that, in the ninjin'yoeito group compared with the control group, the OKT₄ (Th1) levels over time showed smaller decrease after surgery and also other immunological parameters appeared to have better recovery after surgery, which could be misleading. Since the sample size was very small and the extent of surgical invasion is not specified, the data appear to be insufficient to draw a conclusion. Nevertheless, immunopotentiality is one of the important mechanisms of action of ninjin'yoeito, which is one of three major tonifying Kampo formulae. Further RCTs with adequate sample sizes and due consideration given to the extent of surgical invasion are desired.

12. Abstractor and date

Motoo Y, 18 August 2019.