

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

Araki Y, Tanaka T, Ogata Y, et al. Immunological evaluation of the efficacy of Kampo prescription for postoperative patients with colorectal cancer*. *Shinyaku to Rinsho (Journal of New Remedies and Clinic)* 1992; 41: 1670–6 (in Japanese).

1. Objectives

To evaluate the immunostimulation and improvement of nutritional status by ninjin'yoeito (人参養榮湯) in postoperative patients with colorectal cancer.

2. Design

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

3. Setting

One university hospital (1st Department of Surgery, Kurume University), Japan.

4. Participants

Twenty-three postoperative patients with colorectal cancer on chemotherapy.

5. Intervention

Arm 1: TSUMURA Ninjin'yoeito (人参養榮湯) Extract Granules 9.0 g/day from the start of postoperative oral feeding (n=12).

Arm 2: no treatment (n=11).

6. Main outcome measures

Peripheral blood white blood cell (WBC) count, lymphocyte count, percentage of T cells (%), phytohemagglutinin (PHA) lymphocyte transformation, lymphocyte surface markers (CD4, CD8, and CD25), NK cell activity (%), and interleukin (IL)-2 responsiveness, measured preoperatively, and at postoperative week 2 and months 3 and 6 as indices of immunological status. Patient prognosis (observation for 3 years and 6 months to 4 years and 4 months) in both arms. Prognostic nutritional index (PNI).

7. Main results

Percent change in lymphocyte count: greater in arm 1 than arm 2 at postoperative week 2 and month 3 ($P<0.05$).

Change in the T cell number (in %): greater in arm 2 than arm 1 ($P<0.05$) at postoperative week 2, but greater in arm 1 than arm 2 ($P<0.05$) at postoperative months 3 and 6.

Percent change in PHA-stimulated lymphocyte proliferation: greater in arm 1 than arm 2 at postoperative month 6 ($P<0.05$).

Change in NK cell activity (in %) and prognostic nutritional index (PNI): no significant difference between arms.

Change in the number of CD4- and CD8-positive cells (in %) and IL-2 responsiveness ratio: all tended to be greater in arm 1 than arm 2 at postoperative week 2 and month 3.

IL-2 receptor-positive cell ratio: tended to be greater in arm 1 than arm 2 at postoperative week 2 and month 6. At postoperative month 6, there was a significant reduction from preoperative value in arm 1 ($P<0.05$).

8. Conclusions

Ninjin'yoeito significantly promotes improvement of lymphocyte count and PHA-stimulated lymphocyte proliferation in postoperative patients with colorectal cancer, suggesting its role as a possible biological response modifier.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

None.

11. Abstractor's comments

This study demonstrated that administration of ninjin'yoeito increased lymphocyte count, the percentage of T lymphocytes, and PHA-stimulated lymphocyte proliferation but had no effect on NK cell activity, IL-2 responsiveness ratio, or IL-2 receptor-positive cell ratio (indices of unknown immunological significance), or nutritional state (PNI). (Although the authors concluded that NK cell activity was enhanced, a similar increase was noted in the control group; thus, it is impossible to conclude that NK cell activity was enhanced by the Kampo medicine.) However, certain cellular immune functions may have been stimulated one of the mechanisms underlying Kampo medicine activity.

12. Abstractor and date

Hoshino E, 26 April 2009, 1 June 2010, 31 December 2013.