

**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 (人参養栄湯) 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 (人参養栄湯) 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.