

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

Sasaki K, Takashima K, Kitagawa K, et al. Immunostimulation and suppression of liver metastasis by Kampo medicines in postoperative patients with colorectal cancer*. *Progress in Medicine* 1992; 12: 1652–5 (in Japanese).

1. Objectives

To evaluate the suppression of liver metastasis and stimulation of the immune response by shosaikoto (小柴胡湯) in postoperative patients with colorectal cancer.

2. Design

Randomized controlled trial (RCT).

3. Setting

One university hospital (1st Department of Surgery, Sapporo Medical College), Japan.

4. Participants

Twenty postoperative patients with colorectal cancer on chemotherapy.

5. Intervention

Arm 1: administration of TSUMURA Shosaikoto (小柴胡湯) Extract Granules 7.5 g/day started 3–4 weeks postoperatively (n=10).

Arm 2: administration of Krestin (polysaccharide Kureha: PSK) 3 g/day started 3–4 weeks postoperatively (n=10).

6. Main outcome measures

Peripheral blood white blood cell (WBC) count, lymphocyte count, CD3-, CD4-, CD8-, CD57-, CD16-positive cells (%), and phytohemagglutinin (PHA)-stimulated lymphocyte proliferation, measured at baseline, 2, 4, and 12 weeks after administration as immunological indices. Patient prognosis (observation for 3 years and 6 months to 4 years and 4 months) in both arms.

7. Main results

CD4/CD8 ratio: There was no difference between arms.

CD57: At week 2, the percent increase was significantly larger in arm 1 than in arm 2. At week 4, a significant increase from baseline was noted in both arms.

CD16: At weeks 4 and 12, a significant increase from baseline was noted in both arms.

PHA-stimulated lymphocyte proliferation: A significant increase from baseline was noted at weeks 2, 4, and 12 in arm 1 and at week 12 in arm 2.

Prognosis: In arm 1, there was 1 patient with tumor recurrence in the abdominal wall who survived after re-operation and 1 death. In arm 2, there was 1 patient with liver metastasis who died and 1 patient with local recurrence who survived after re-operation.

8. Conclusions

Saiko agents increased PHA-stimulated lymphocyte proliferation and NK cell activity, evaluated by CD57 and CD16, suggesting its immunostimulating effect.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

None.

11. Abstractor's comments

The above immunological findings were in patients on chemotherapy started 3–4 weeks postoperatively. Generally, the immune system is compromised postoperatively because of trauma and malnutrition. Cellular immunity is thought to be reduced for 2–4 weeks postoperatively and restored to preoperative level in 6 weeks. Therefore, it is impossible to conclusively attribute the increase in PHA lymphocyte proliferation and NK activity at 2–12 weeks postoperatively to the effect of shosaikoto or PSK without a no treatment control. Also, there is a wide distribution of disease stages, making it impossible to discuss prognosis. It is necessary to compare two groups of patients with stage III–IV on specified chemotherapy after confirmation of sufficient recovery from surgery: one group treated with Kampo medication and one group without such treatment.

12. Abstractor and date

Hoshino E, 26 April 2009.