

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

Mori T, Tsuchi K, Yokoyama S, et al. Effects of sho-saiko-to (xiao-chai-hu-tang) on thrombocytopenia bei therapy with anti-cancer drugs. *Sanfujinka Chiryō (Obstetrical and Gynecological Therapy)* 1992; 65: 102–5 (in Japanese).

**1. Objectives**

To evaluate the effects of preoperative administration of shosaikoto (小柴胡湯) on thrombocytopenia in gynecologic cancer patients receiving anti-cancer drugs.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

One university hospital (Department of Gynecology and Obstetrics, Kyoto University Hospital) and 12 other hospitals, Japan.

**4. Participants**

Eighty-nine gynecologic cancer patients receiving anti-cancer drugs (ovarian cancer, 68; endometrial cancer, 16; cervical cancer, 5; choriocarcinoma, 1; uterine sarcoma, 1).

**5. Intervention**

Arm 1: administration of TSUMURA Shosaikoto (小柴胡湯) Extract Granules 7.5 g/day for 14 days after white blood cell (WBC) count fell below 3000 (n=49).

Arm 2: no administration of Kampo medicines after WBC count fell below 3000 (n=40).

**6. Main outcome measures**

Peripheral blood leukocytes, platelet count, IgG, IgA, IgM, OKT 4, OKT 8, and NK cell activity before administration of anti-cancer drugs, on the day the WBC fell below 3000 and 14 days after the WBC count fell below 3000, as well as days to recovery of the WBC count to  $\geq 3000$ .

**7. Main results**

Days to recovery of the WBC count to  $\geq 3000$ : no significant difference between groups.

Increase in platelet count for 14 days: greater in arm 1 than arm 2 ( $P < 0.05$ ).

IgG, IgA, IgM, OKT 4, OKT 8, and NK cell activity: no significant difference between groups.

**8. Conclusions**

Administration of shosaikoto in patients with leukopenia associated with anti-cancer therapy leads to the recovery of platelet count.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned in the article.

**11. Abstractor's comments**

The authors reported that shosaikoto was effective in raising the platelet count in patients with thrombocytopenia associated with anti-cancer drugs. However, the platelet counts had decreased to within the normal range and these decreases might not be due to myelosuppression. The platelet count reduction was therefore not by definition indicative of "thrombocytopenia associated with anti-cancer drugs." Shosaikoto was started at the time the WBC count had fallen below 3000. Inasmuch as lymphocyte count may be decreased by undernutrition, granulocyte count should be used as a measure of myelosuppression. There is a lack of consistency in terms of endpoints, that is, for the WBC count, it was the time to recovery to  $\geq 3000$ , while for the platelet count, it was the difference in values at the time and 14 days after the WBC count fell below  $< 3000$ . It is also not clear why the duration of treatment with shosaikoto is two weeks. An appropriate strategy for analysis would be to perform serial WBC and platelet counts beginning just after the start of shosaikoto, and analyze these measurements.

**12. Abstractor and date**

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