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

Reference

Inoue S, Kuwahara H, Kato Y, et al. Thrombopoietic and leukopoietic effects of a traditional Chinese herbal medicine, formula reverti lienalis compositae (Japanese name: *Kami-kihi-to TJ-137*) in cancer patients. *Biotherapy* 1998; 12: 1071-6 (in Japanese with English abstract). MOL, MOL-Lib

1. Objectives

To evaluate the effect of kamikihito (加味帰脾湯) on thrombocytopenia and leukopenia in patients receiving anti-cancer drugs.

2. Design

A randomized cross-over controlled trial (RCT-cross over).

3. Setting

Two hospitals, Japan.

4. Participants

Six patients with gynecological cancer (four with ovarian cancer, one with endometrial cancer, and one with cervical cancer) receiving cisplatin-based anti-cancer therapy.

5. Intervention

Since allocation of patients to treatment arms is not mentioned, the treatment arms are described in terms of treatment regimen. Cycles of anti-cancer therapy up to the fourth cycle in each patient were randomly assigned to either treatment or no treatment with TSUMURA Kamikihito (加味帰脾湯) Extract Granules (7.5 g/day) (Granisetron was administered to all patients for antiemetic purposes, and granulocyte colony-stimulating factor (G-CSF) was prophylactically administered in all cycles in all 6 patients except 1.

Arm 1: administration of TSUMURA Kamikihito (加味帰脾湯) Extract Granules 7.5 g/day during the treatment period (n=6, 11 cycles).

Arm 2: no administration of kamikihito (加味帰脾湯) (n=6, 12 cycles).

6. Main outcome measures

Peripheral blood platelet and white blood cell (WBC) counts, minimum value of hemoglobin, severity of adverse drug reactions (WHO grade), decrease in area under the platelet-time curve (area of the platelet-time curve below the lower limit of the normal range [130,000/μ]), dose of G-CSF.

7. Main results

The minimum platelet count was higher in treated cycles (arm 1) than in untreated cycles (arm 2) in 5 of 6 patients (P=0.0127). The area of the decrease in platelet count was smaller in arm 1 than in arm 2 (P=0.0126). The minimum value of WBC count was higher in arm 1 than in arm 2 (P=0.0025).

The dose of G-CSF was lower in arm 1 than in arm 2 (significance of difference not tested).

There was no significant difference in the minimum value of hemoglobin between arms.

8. Conclusions

Kamikihito is expected to prevent thrombocytopenia and leukopenia associated with anti-cancer drugs.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

Although this report is attractive in that a Kampo medicine can suppress or reverse thrombocytopenia, leukopenia (granulocytopenia), and anemia associated with anti-cancer drugs, establishment of the criteria for patient entry requires careful consideration. The present study failed to consider platelet count at the baseline of each cycle. Baseline platelet count was higher in kamikihito-treated cycles in all 6 patients except 1, and quite different between arms. Naturally, decrements due to anti-cancer treatment are smaller when baseline platelet count (and probably WBC count as well) is higher. Even though cycles were randomly assigned to Kampo treatment or no treatment, the evidence in this report is not sufficiently convincing, given that the differences in background values between arms were not considered in the analysis of the results.

12. Abstractor and date

Hoshino E, 26 April 2009, 6 January 2010, 31 December 2013.