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

Reference

Matsuda C, Munemoto Y, Mishima H, et al. Double-blind, placebo-controlled, randomized phase II study of TJ-14 (Hangeshashinto) for infusional fluorinated-pyrimidine-based colorectal cancer chemotherapy-induced oral mucositis. *Cancer Chemotherapy and Pharmacology* 2015; 76: 97-103.

1. Objectives

To verify the clinical effects of hangeshashinto (半夏瀉心湯) for chemotherapy-induced oral mucositis.

2. Design

Double-blind, randomized controlled trial (DB-RCT).

3. Setting

Ten centers including a medical care center, Japan.

4. Participants

Ninety-three participants administered a fluorinated-pyrimidine-based anti-cancer agent for colorectal cancer, who developed moderate-to severe chemotherapy-induced oral mucositis (WHO grade ≥1).

5. Intervention

Arm 1: TSUMURA Hangeshashinto (半夏瀉心湯) Extract Granules 7.5g/day (2.5g t.i.d.) (n=46) starting administration together with the start of chemotherapy cycle 2 for 2 weeks.

Arm 2: Placebo formulation (n=47).

In each arm, administration continued for 2 weeks from commencement of chemotherapy.

6. Main outcome measures

Oral mucositis symptoms and objective findings at screening and on days 3, 5, 7, 9 and 14 of chemotherapy cycle 2.

7. Main results

In arm 1, 3 participants were excluded: 43 were administered hangeshashinto. There was no significant difference between the hangeshashinto group (48.8%) and the placebo group (57.4%) for occurrence of oral mucositis of grade 2 or higher. However, the mean period to improvement of oral mucositis of grade 2 or higher was significantly shorter in the hangeshashinto group (5.5 days) compared to the placebo group (10.5 days) (P＝0.018).

8. Conclusion

Hangeshashinto has a therapeutic effect as it accelerates improvement of oral mucositis of grade 2 or higher induced by an anti-cancer agent.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

There was no significant difference in occurrence of adverse effects between the placebo group and the hangeshashinto group.

11. Abstractor's comments

This study compared the therapeutic effect of hangeshashinto extract granules with placebo on oral mucositis induced by an anti-cancer agent. It found that administering hangeshashinto shortened the period until recovery from oral mucositis of grade 2 or higher, suggesting it fulfills a certain role as a therapeutic drug, so it is a clinically significant study. The authors investigate its preventive effect against oral mucositis by starting administration of hangeshashinto together with the start of the anti-cancer agent therapy, however, the occurrence of oral mucositis was the same as the placebo, which showed that preventive administration was not effective. A characteristic of Kampo medicine is that it takes a presymptomatic approach with the existence of *sho* (証, patterns) underlying it, so it would be advisable to allocate participants to groups based on their pattern if possible, when examining its preventive effects.

12. Abstractor and date

Ushiroyama T, 16 January 2017.