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

Reference

Aoyama T, Nishikawa K, Takiguchi N, et al. Double-blind, placebo-controlled, randomized phase II study of TJ-14 (hangeshashinto) for gastric cancer chemotherapy-induced oral mucositis. *Cancer Chemotherapy and Pharmacology* 2014; 73: 1047-54. CENTRAL ID: CN-00993423, Pubmed ID: 24652604

1. Objectives

To evaluate the efficacy of hangeshashinto (半夏瀉心湯) for gastric cancer chemotherapy-induced oral mucositis.

2. Design

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

3. Setting

Ten facilities (four university hospitals and 6 hospitals).

4. Participants

Ninety-one patients with oral mucositis induced by gastric cancer chemotherapy rated at grade 1 or more on CTC-AE v4.0.

5. Intervention

Arm 1: TSUMURA Hangeshashinto (半夏瀉心湯) Extract Granules (2.5 g t.i.d.) taken until the start of the next round of chemotherapy (n=45).

Arm 2: Placebo administration group (n=46).

6. Main outcome measures

Severity of oral mucositis, its frequency and duration.

7. Main results

The frequency of oral mucositis of grade 2 or more was 40% in the hangeshashinto group (arm 1) and 41.3% in the control group (arm 2), so no significant between-group difference was found. Nor was any significant between-group difference found for oral mucositis duration (14 days in arm 1 and 16 days in arm 2). However, median oral mucositis duration among all grades was 9.0 days in arm 1 and 17.0 days in arm 2: although this was not a significant difference, oral mucositis duration tended to be shorter in the hangeshashinto group compared to the placebo group (P=0.290).

8. Conclusions

Hangeshashinto tends to shorten the duration of oral mucositis induced by gastric cancer chemotherapy.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Being an adverse effect induced by an anticancer drug, no adverse event attributable to hangeshashinto was observed.

11. Abstractor's comments

Being a double-blind RCT using placebo, this is a high-quality study that tested the effects of hangeshashinto for oral mucositis induced by gastric cancer chemotherapy. Unfortunately there was no significant difference in frequency or duration of oral mucositis of grade 2 or more, although hangeshashinto did tend to shorten oral mucositis duration among all grades. The authors point to a decrease in the anticancer dose as a possible reason why no significant difference was found. Yet the authors mention the need for a larger scale phase III trial in which the anticancer drug dose is not decreased, which is a valid observation. This follows the principle of "Kampo for the successful accomplishment of standard treatment": alleviating the oral mucositis with hangeshashinto allows for the anticancer drug to demonstrate its inherent effect to the full, without the need to decrease the dose. Further progress in this research is anticipated.

12. Abstractor and date

Motoo Y, 31 March 2017