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

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1. Objectives

To evaluate the safety and efficacy of hangeshashinto (半夏瀉心湯) (TJ-14) for CPT-11-induced diarrhea during combination chemotherapy with cisplatin (CDDP) plus irinotecan hydrochloride (CPT-11) for advanced non-small-cell lung cancer (NSCLC).

2. Design

Randomized controlled trial using envelopes for allocation (RCT-envelope).

3. Setting

One hospital; the authors belong to the Department of Respiratory Disease, Tochigi Cancer Center, Japan.

4. Participants

From among inpatients with NSCLC who received dual therapy with CDDP plus CPT-11 from November 1993 through December 1996, forty one patients who met the following selection criteria were enrolled: 1) treatment-naïve with unresectable NSCLC (stage III, IV); 2) performance status 0 to 2; 3) preserved major organ function; 4) 75 years or younger; and 5) informed consent. Patients with serious complications, diarrhea, severe pleural effusion, or symptomatic cerebral metastasis were excluded from the study.

5. Intervention

Arm 1: treatment with TSUMURA Hangeshashinto (半夏瀉心湯) Extract Granules (TJ-14) 2.5 g t.i.d. before meals in 18 patients.

Arm 2: no treatment in 23 patients.

In the arm 1, hangeshashinto was administered every day from at least 3 days before through 21 days or more after the start of chemotherapy.

6. Main outcome measures

Stool properties and frequency of defecation, presence and severity of abdominal pain associated with defecation, presence or absence of bowel movements at night and bloody diarrhea.

7. Main results

The onset and the highest daily frequency of diarrhea were respectively recorded at 6.3 and 9.2 days after the start of chemotherapy in arm 1, and at 5.9 and 9.0 days in arm 2. During the first cycle of chemotherapy, the severity of diarrhea was significantly improved and the incidence of grade 3 or higher diarrhea was lower in arm 1 than in arm 2. The number of diarrhea episodes and the duration (in days) of diarrhea were not significantly different between the two arms.

8. Conclusions

Hangeshashinto is effective for preventing and relieving CPT-11-induced diarrhea in advanced NSCLC.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Mild constipation was reported in 2 hangeshashinto-treated patients. Other significant adverse effects were not observed.

11. Abstractor's comments

This clinical study indicated that the concomitant use of hangeshashinto is effective for diarrhea, which can occur during chemotherapy containing CPT-11. This study lacked a placebo control group and was not double-blinded. In a study using Kampo medicines as a control, it is difficult to prepare the placebo because Kampo medicines have specific textures and smells. Nonetheless, double-blind design should be considered in order to improve the quality of study. "

12. Abstractor and date

Arai M, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.