

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

Miyauchi H. A comparative study of the preventive effects of hangeshashinto and oral alkalizer for delayed diarrhea in chemotherapy for colorectal cancer (FOLFILI)\*. *Progress in Medicine* 2012; 32: 628-9 (in Japanese). [MOL](#), [MOL-Lib](#)

**1. Objectives**

To compare the preventive effects of hangeshashinto (半夏瀉心湯) for delayed diarrhea following administration of CPT-11 for colorectal cancer.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

No mention of participating centers (the authors are from the Department of Frontier Surgery, Graduate School of Medicine, Chiba University), Japan.

**4. Participants**

Thirty patients (age range: 20–80 years) with advanced recurrent colorectal cancer.

**5. Intervention**

Arm 1: oral administration of hangeshashinto (半夏瀉心湯) (manufacturer not specified) 7.5 g/day during FOLFILI-3 treatment (n=14).

Arm 2: administration of oral alkalizers (sodium bicarbonate 1.8 g and ursodeoxycholic acid 300 g) from the first day of FOLFILI-3 treatment (n=15).

**6. Main outcome measures**

Grade of diarrhea, grade of adverse events other than diarrhea, drug compliance, response rate, treatment duration.

**7. Main results**

No significant difference between arms 1 and 2 was noted in diarrhea grade (3/14 [21.4%] participants in arm 1 and 4/15 participants [26.7%] in arm 2 scored grade III or higher), neutropenia grade (4/14 [28.5%] participants in arm 1 and 6/15 participants [40%] in arm 2 scored grade III or higher), drug compliance (81.2% in arm 1, with 87.5% for sodium bicarbonate and 96.8% for ursodeoxycholic acid in arm 2), antitumor effect (complete response [CR] in no participants and partial response [PR] in six participants in arm 1; CR in two participants and PR in eight participants in arm 2), response rate/disease control rate (response rate of 46.2% and disease control rate of 92.3% in arm 1; response rate of 71.4% and disease control rate of 100% in arm 2), and number of FOLFILI cycles (16.1 in arm 1 and 14.5 in arm 2).

**8. Conclusions**

Oral alkalizer and hangeshashinto have the same preventative effect on delayed diarrhea in FOLFILI.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

The authors originally held the notion that oral alkalizer prevented delayed diarrhea, which is a dose-limiting toxicity (DLT) and an adverse effect in patients receiving CPT-11 for advanced recurrent colorectal cancer. This study evaluated the previously reported inhibitory effect of hangeshashinto compared with oral alkalizer (the control group) and found no difference in their inhibitory effects. However, there is no indication that intestinal alkalizers taken orally do in fact prevent delayed diarrhea from CPT-11. A trial that uses a therapy without established efficacy as a control has little significance. It is of fundamental importance to clarify the clinical effectiveness by including a hangeshashinto group and a non-hangeshashinto group in the trial.

**12. Abstractor and date**

Hoshino E, 31 December 2013.