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

Reference

Katsuno H, Maeda K, Kaiho T, et al. Clinical efficacy of Daikenchuto for gastrointestinal dysfunction following colon surgery: a randomized, double-blind, multicenter, placebo-controlled study (JFMC39-0902). *Japanese Journal of Clinical Oncology* 2015; 45: 650-6.

1. Objectives

To evaluate the efficacy of daikenchuto (大建中湯) for gastrointestinal dysfunction following colon surgery.

2. Design

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

3. Setting

Fifty-one centers, including university hospitals.

4. Participants

Three hundred and eighty-six patients, colon cancer stage I-IIIb, T=1-3, N=0-2, M=0, who had colon resection by laparotomy.

5. Intervention

Among 386 patients, 354 were allocated.

Arm 1: TSUMURA Daikenchuto (大建中湯) Extract Granules (n=181) 15g/day (5g t.i.d.) administerd orally from day 2 to day 8 after surgery.

Arm 2: Placebo granules (n=173) 15g/day (5g t.i.d.) administerd orally for the same period as above.

Administration from day 2 to day 8 after surgery.

6. Main outcome measures

Time until first flatus after surgery, flatus frequency per day from day 2 to day 8 after surgery, stool shape, blood CRP level, patient QOL score using GSRS.

7. Main results

In arm 1, there were 7 dropouts (174 were analyzed), while in arm 2 there were 11 dropouts with 162 being analyzed. No significant difference was observed for time until first flatus after surgery, blood CRP level, or GSRS score. Flatus frequency per day from day 2 to day 8 after surgery was enhanced in the daikenchuto group from day 2 to 6, but decreased on days 7 and 8. Frequency of bowel movement was significantly lower compared to the placebo group on day 8 after surgery (P=0.024).

8. Conclusion

Drug efficacy is observed in daikenchuto for 1 week after surgery, but it is slow, and no clinical significance is observed for patients following laparotomy.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

7 adverse events of grade 3 or higher occurred among the trial subjects, but no significant difference between the groups was observed.

11. Abstractor's comments

No significant difference was found in time until flatus, stool shape, or QOL score by taking daikenchuto after laparotomy. Nevertheless, there was a strong flatus trend in the daikenchuto group up to day 6 after surgery, but the flatus trend was then found to reverse, decreasing on days 7 and 8. These results correspond to a sense of clinical usability, and it may be possible to elicit significant differences by increasing the number of participants and reexamining them. And in regard to the problem of when to end daikenchuto use started after surgery, this paper also suggests the possibility that it might be appropriate to divide the time after surgery into weeks.

12. Abstractor and date

Nakata H, 2 February 2017.