11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

References

Nishida T. Effect of rikkunshito on gastrointestinal function in patients after gastrectomy*. *Progress in Medicine* 2006; 26: 3224-5 (in Japanese). MOL, MOL-Lib

Takahashi T, Endo S, Nakajima K, et al. Effect of Rikkunshito, a Chinese herbal medicine, on stasis in patients after pylous-preserving gastrectomy. *World Journal of Surgery* 2009; 33: 296-302. CENTRAL ID: CN-00686725, Pubmed ID: 19082653

1. Objectives

To evaluate the efficacy of TSUMURA Rikkunshito (六君子湯) Extract Granules for delayed excretion after pylorus-preserving gastrectomy (PPG).

2. Design

Osaka University Hospital, Japan.

3. Setting

Randomized controlled trial (cross-over) (RCT cross-over).

4. Participants

Eleven patients who underwent pylorus-preserving gastrectomy.

5. Intervention

Arm 1: TSUMURA Rikkunshito (六君子湯) Extract Granules 2.5 g t.i.d. for 4 weeks and then not treated with TSUMURA Rikkunshito (六君子湯) Extract Granules for 4 weeks (n=4).

Arm 2: not treated with TSUMURA Rikkunshito (六君子湯) Extract Granules for 4 weeks and then treated with TSUMURA Rikkunshito (六君子湯) Extract Granules 2.5 g t.i.d. for 4 weeks (n=7).

6. Main outcome measures

Gastrointestinal quality of life (QOL) index (GIQLI), stasis-related symptom score, Sigstad score, gastrointestinal excretion scintigram.

7. Main results

While there was no significant between-arm difference in the GIQLI and Sigstad score (dumping syndrome), the stasis-related symptom score significantly decreased on treatment in arm 1. In the scintigram, the gastric residual rate of solids (but not liquids) excretion decreased on treatment with TSUMURA Rikkunshito (六君子湯) Extract Granules.

8. Conclusions

Treatment with TSUMURA Rikkunshito Extract Granules is effective for delayed gastric excretion of solids after PPG.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No drug-related or protocol-defined adverse event was reported.

11. Abstractor's comments

This is a clinical trial of high clinical significance in that scintigraphy was used to objectively evaluate excretion of liquids and solids separately. However, the study design, including randomization of patients and sample size, is questionable. It is desirable to conduct a high-quality RCT using an adequate sample size. In the previous version of Evidence Reports of Kampo treatment, structured abstract for this trial was developed and published based on the article by Nishida (2006), however, this trial was subsequently published as the reference above, and structured abstract was reconstructed on the basis of this new article.

12. Abstractor and date

Kogure T, 26 January 2009, 1 June 2010, 31 December 2013.