

**11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases****Reference**

Morita T. Effects of Rikkunshito (TJ-43) on gastroesophageal reflux, esophageal motor functions and salivary secretion: placebo-controlled double-blind study. *Nikkei Medical (Supplement)* 2010; 8: 27 (in Japanese).

**Morita T, Furuta K, Adachi K, et al. Effects of Rikkunshito (TJ-43) on esophageal motor function and gastroesophageal reflux. *Journal of Neurogastroenterology and Motility* 2012; 18: 181-6. Pubmed ID: 22523727**

**1. Objectives**

To evaluate the effects of rikkunshito (六君子湯) on esophageal motor function and gastroesophageal reflux.

**2. Design**

Randomized controlled crossover trial (RCT - cross over).

**3. Setting**

Shimane University Hospital, Japan.

**4. Participants**

Ten healthy people.

**5. Intervention**

Arm 1: TSUMURA Rikkunshito (六君子湯) Extract Granules 7.5 g/day for 7 days, no administration for one week, then placebo for 7 days (number of participants not specified).

Arm 2: placebo for 7 days, no administration for one week, then TSUMURA Rikkunshito (六君子湯) Extract Granules 7.5 g/day for 7 days (number of participants not specified).

**6. Main outcome measures**

Lower esophageal sphincter (LES) resting pressure, esophageal peristaltic contraction pressure after drinking water, postprandial gastroesophageal reflux frequency.

**7. Main results**

LES resting pressure was significantly higher in supine position with rikkunshito administration compared to placebo administration ( $P=0.047$ ), but there was no significant difference when in sitting position. No significant between-group difference attributable to rikkunshito administration was observed for esophageal peristaltic contraction pressure after drinking water or frequency.

**8. Conclusions**

Rikkunshito raised LES resting pressure in healthy subjects in supine position, but not in sitting position, and had no effect on esophageal peristaltic contraction pressure after drinking water or postprandial gastroesophageal reflux frequency.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

Gastroesophageal reflux has been increasing in recent years, especially among the elderly, prompting hope that rikkunshito would be effective for patients in whom it could not be satisfactorily controlled with proton pump inhibitors. This study in healthy subjects is the first step toward generating that evidence base. Rikkunshito raised LES resting pressure in supine position, but there was no significant difference in sitting position, and no significant difference in any of the other outcomes: it was a study of healthy young people (mean age: 22.8 years), so the results should be accepted for what they are. However, there was no mention of the numbers of participants being allocated by a randomized process. Based on these outcomes, the authors will hopefully repeat this investigation not with healthy subjects, but with actual gastroesophageal reflux patients, as the authors themselves mention in the paper.

**12. Abstractor and date**

Motoo Y, 31 December 2012, 31 December 2013..