

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

Koide A. Establishment of new treatment strategy for non-erosive reflux disease (endoscopy-negative gastroesophageal reflux disease) – potential of rikkunshito\*. *MedicalQ* 2006; 187 (in Japanese).

**1. Objectives**

To evaluate the efficacy of TSUMURA Rikkunshito (六君子湯) Extract Granules for treatment of non-erosive reflux disease (NERD) unresponsive to proton pump inhibitors (PPIs).

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

No description of the setting is available; the author belongs to a clinic, Japan.

**4. Participants**

One hundred and eighteen patients with PPI-unresponsive NERD.

**5. Intervention**

Arm 1: treatment with omeprazole (200 mg), as the PPI alone group, n=37.

Arm 2: treatment with TSUMURA Rikkunshito (六君子湯) Extract Granules (7.5 g), as the rikkunshito alone group, n=39.

Arm 3: treatment with omeprazole (200 mg) and TSUMURA Rikkunshito (六君子湯) Extract Granules (7.5 g), as the PPI + rikkunshito (六君子湯) group, n=42.

The duration of treatment was 4 weeks in all arms.

**6. Main outcome measures**

Gastrointestinal Symptom Rating Scale (GSRS) score (which includes ratings of overall gastrointestinal symptoms, reflux, abdominal pain, and dyspepsia).

**7. Main results**

Scores of overall gastrointestinal symptoms and reflux were significantly more improved in arm 3 than in arms 1 and 2; the scores in arms 1 and 2 were similar. The abdominal pain score was similarly improved in all three arms. Dyspepsia score was significantly more improved in arms 2 and 3 than in arm 1, but the scores in arms 2 and 3 were similar.

**8. Conclusions**

TSUMURA Rikkunshito Extract Granules is effective for relieving clinical symptoms of NERD.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

This study deserves praise for conducting a RCT using TSUMURA Rikkunshito Extract Granules as a study drug in patients with treatment-unresponsive NERD. Unfortunately, the mechanism was not discussed, and endoscopic findings and other features were not mentioned. Publication of the latter is expected in the future.

**12. Abstractor and date**

Kogure T, 26 January 2009.