

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.