

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

Takemoto T, Matsuda K, Tada M, et al. Clinical evaluation of the efficacy of TJ-43 Tsumura Rikkunshi-To on gastritis with abdominal symptoms - a multicenter group study in comparison with cetraxate -. *Shokakika (Gastroenterology)* 1990; 12: 223-34 (in Japanese with English abstract).

**1. Objectives**

To evaluate the efficacy and safety of TSUMURA Rikkunshito (六君子湯) for treating gastritis in a comparison with cetraxate as a control.

**2. Design**

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

**3. Setting**

Sixteen institutions including Yamaguchi University Hospital, Japan.

**4. Participants**

Seventy patients who were diagnosed with atrophic, superficial, or erosive gastritis by endoscopy and had epigastric complaints such as abdominal pain or bloating.

**5. Intervention**

Arm 1: treatment with TSUMURA Rikkunshito (六君子湯) Extract Granules 2.5 g t.i.d. before meals for 4 weeks (n=38).

Arm 2: treatment with cetraxate hydrochloride 200 mg q.i.d. before meals and bedtime for 4 weeks (n=32).

**6. Main outcome measures**

Subjective symptoms and endoscopic findings.

**7. Main results**

The rate of improvement in fatigue was significantly higher in arm 1 than in arm 2. The rate of improvement in endoscopically evaluated erosive disease, rate of global improvement in symptoms (both subjective and endoscopically assessed), and the utility rating tended to be higher in arm 1. The overall rate of improvement in subjective symptoms was significantly higher in arm 1.

**8. Conclusions**

TSUMURA Rikkunshito seems to have an excellent clinical efficacy for treating gastritis with epigastric disturbance.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

No adverse drug reactions occurred.

**11. Abstractor's comments**

In the present paper, the clinical utility of TSUMURA Rikkunshito in comparison with that of cetraxate (the control) is determined as treatment for gastritis. It was a multicenter controlled trial, similar to that described in "Miyoshi A, Kaneko E, Nakazawa S, et al. Clinical evaluation of TJ-43 TSUMURA Rikkunshito in the treatment of gastritis (acute gastritis and acute exacerbation of chronic gastritis) - a multicenter comparative study using sodium azulene sulfonate as a control - \*. *Shindan to Chiryō (Diagnosis and Treatment)* 1991; 79: 789-810 (in Japanese)". Both studies showed similar results, but the statistical significance of differences was weaker in the present study. This discrepancy might be due to the small number of patients enrolled.

**12. Abstractor and date**

Oikawa T, 19 September 2008, 1 June 2010.