

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

Miyoshi A, Yachi A, Masamune O, et al. Clinical evaluation of TJ-43 TSUMURA Rikkunshito in the treatment of indefinite complaints of gastrointestinal disorders including chronic gastritis - a multicenter comparative study using cisapride as a control - \*. *Progress in Medicine* 1991; 11: 1605-31 (in Japanese).

**1. Objectives**

To evaluate the efficacy and safety of TSUMURA Rikkunshito (六君子湯), using cisapride as a control, in the treatment of indefinite complaints of gastrointestinal disorders including chronic gastritis.

**2. Design**

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

**3. Setting**

Fifty institutions including university hospitals, Japan.

**4. Participants**

Two hundred and forty-eight patients who had so-called “non-ulcer dyspepsia” (e.g., chronic atrophic gastritis) with 2 or more indefinite complaints of gastrointestinal disorders, associated with possible impairment of gastric motility. Of 248 participants, 215 were included in the analysis.

**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=111).

Arm 2: treatment with cisapride 2.5 mg t.i.d. before meals for 4 weeks (n=104).

**6. Main outcome measures**

Subjective and objective symptoms.

**7. Main results**

The improvement in certain individual subjective symptom scores (i.e., scores for anorexia [at 3 weeks], epigastric pain [at 2, 3, and 4 weeks], abdominal discomfort [at 4 weeks], cold extremities [at 2, 3, and 4 weeks], and lightheadedness [at 2 weeks]), global score, and utility rating were significantly higher in arm 1 than in arm 2. The improvement in the ratings for belching (at 1 and 2 weeks) and tenderness (at 1 week) were significantly higher in arm 2 than in arm 1.

**8. Conclusions**

TSUMURA Rikkunshito is more efficacious than cisapride and is clinically useful in the treatment of indefinite complaints of gastrointestinal disorders including chronic gastritis.

**9. From Kampo medicine perspective**

For patients aged 60 or older and those who are thin or overweight, improvement in symptom scores tended to be higher in arm 1, supporting the effectiveness of rikkunshito for *kyo-sho* (虚証, deficiency pattern).

**10. Safety assessment in the article**

Two patients discontinued treatment owing to leg discomfort and diarrhea, respectively. There was no significant between-arm difference in the rate of adverse drug reactions and in global safety score.

**11. Abstractor’s comments**

This paper describes an evaluation of the clinical utility of TJ-43 TSUMURA Rikkunshito using cisapride as a control in the treatment of gastritis. It was a large, multicenter clinical trial. It is safe to say that evidence for the efficacy of rikkunshito treatment was established by this and another paper “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)”. Like the the approach of the latter study, that of the present study may have been progressive for its time, since Kampo medical parameters, such as “tension of the abdominal wall” and “splashing sounds in the gastric region”, were also evaluated in the analysis.

**12. Abstractor and date**

Oikawa T, 19 September 2008, 1 June 2010.