

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

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).

1. Objectives

To determine the efficacy and safety of rikkunshito (六君子湯) for treating gastritis (acute gastritis and acute exacerbation of chronic gastritis).

2. Design

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

3. Setting

Forty-five institutions including Shizuoka General Hospital, Japan.

4. Participants

Two hundred and thirty-six patients with gastritis (acute gastritis or acute exacerbation of chronic gastritis) in whom 3 or more indefinite complaints of epigastric distress, were observed and peptic ulcer and gastric cancer were excluded by endoscopy or radiography. Of 236 participants, 207 were included in the analysis population.

5. Intervention

Arm 1: treatment with TSUMURA Rikkunshito (六君子湯) Extract Granules 2.5 g t.i.d. before or between meals for 4 weeks (n=109).

Arm 2: treatment with Marzulene-S Granules 2 g/day in three divided doses for 4 weeks (n=98).

6. Main outcome measures

Subjective symptoms and endoscopic findings.

7. Main results

The improvement in symptom ratings for anorexia (at 1 week), epigastric pain (at 2 and 4 weeks), abdominal discomfort (at 2 weeks), and fatigability (at 1 and 4 weeks) were significantly greater in arm 1. The improvement in endoscopically assessed erosion was significantly higher in arm 1. The overall improvement in endoscopic findings at 4 weeks, and improvements in the global symptom score and global utility rating at 4 weeks were significantly greater in arm 1.

8. Conclusions

TSUMURA Rikkunshito is clinically useful for treating gastritis (acute gastritis and acute exacerbation of chronic gastritis) as it resulted in greater improvements compared with Marzulene-S.

9. From Kampo medicine perspective

Rikkunshito tended to result in greater improvements compared with the control drug in patients who had “decreased strength and fatigability”, “choking sensation in the epigastric region”, “low tension of the abdominal wall” and “splashing sounds in the gastric region”.

10. Safety assessment in the article

Only one adverse drug reaction occurred—skin rash in one patient who consequently discontinued treatment.

11. Abstractor’s comments

This paper describes a clinical evaluation of TSUMURA Rikkunshito in the treatment of gastritis (acute gastritis and acute exacerbation of chronic gastritis). This study triggered a series of clinical trials on rikkunshito. Notably, Kampo medical findings, such as “tension of the abdominal wall” and “splashing sounds in the gastric region”, were also included in the analysis. The experimental approach of this study may have been progressive for that time.

12. Abstractor and date

Oikawa T, 19 September 2008, 1 June 2010.