

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

Kawamura S, Okita K, Tada M, et al. Clinical comparison of TSUMURA Rikkunshito and sulpiride in the treatment of indefinite complaints of epigastric distress - mainly the antidepressive effect and the improvement of gastric emptying -*. *Progress in Medicine* 1992; 12: 1156-62 (in Japanese with Chinese abstract).

1. Objectives

To evaluate the efficacy and safety of TSUMURA Rikkunshito (六君子湯) compared with sulpiride for treating epigastric indefinite complaints complicated by depression.

2. Design

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

3. Setting

The study appears to be multicenter, but details are not available, Japan.

4. Participants

Twenty-eight patients with indefinite complaints of epigastric distress and depression.

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=15).

Arm 2: treatment with sulpiride 150 mg t.i.d. after meals for 4 weeks (n=13).

6. Main outcome measures

Subjective symptoms, gastric emptying, and score on the SRQ-D (self-rating questionnaire for depression; the test for masked depression).

7. Main results

The improvement in subjective symptoms score was greater, but not significantly greater, in arm 1 than in arm 2. The improvement in gastric emptying score was significantly greater in arm 2. The improvement in SRQ-D score tended to be greater in arm 2. The utility score was high in both arms.

8. Conclusions

TSUMURA Rikkunshito presumably has an antidepressive effect comparable to that of sulpiride in the treatment of indefinite complaints of epigastric distress complicated by depression.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This paper describes a comparison of the clinical utility of TSUMURA Rikkunshito and sulpiride in the treatment of indefinite complaints of epigastric distress complicated by depression. The study is appreciated because, in addition to subjective symptoms, objective outcome measures (e.g., gastric emptying and SRQ-D scores) were adopted and analyzed. However, the inclusion criteria are somewhat ambiguous and the number of patients enrolled is small, making it difficult to draw a definite conclusion. Although the authors stated "rikkunshito has an antidepressive effect comparable to that of sulpiride", this conclusion may be an exaggeration.

12. Abstractor and date

Oikawa T, 19 September 2008, 1 June 2010.