

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

Oka T, Tamagawa Y, Hayashida S, et al. Rikkunshi-to attenuates adverse gastrointestinal symptoms induced by fluvoxamine. *Biopsychosoc Medicine* [Internet] 2007 [cited 2008 Dec 31]; 1: 21. Available from: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2204024> DOI: 10.1186/1751-0759-1-21. Ichushi Web ID: 2008214687

1. Objectives

To evaluate the clinical effect of rikkunshito (六君子湯) on gastrointestinal adverse reactions induced by fluvoxamine, an antidepressant.

2. Design

Randomized controlled trial (RCT).

3. Setting

University of Occupational and Environmental Health Hospital, Japan.

4. Participants

Fifty patients with depressive disorder (mean age, 40.2 years).

5. Intervention

Arm 1: treatment with fluvoxamine 150 mg/day (escalating from 50 mg/day) and TSUMURA Rikkunshito (六君子湯) Extract Granules 7.5 g/day for 8 weeks, n=25.

Arm 2: treatment with fluvoxamine 150 mg/day (escalating from 50 mg/day) alone for 8 weeks, n=25.

6. Main outcome measures

Gastrointestinal symptoms (assessed by Gastrointestinal Symptom Rating Scale [GSRS] score) and depressive symptoms (by Self-rating Depression Scale [SDS] score).

7. Main results

Overall gastrointestinal symptoms due to fluvoxamine treatment were significantly relieved to a greater extent in arm 1 (GSRS total score, 1.97 ± 0.81) than in arm 2 (2.52 ± 0.99). No significant between-arm difference was observed in post-treatment SDS score.

8. Conclusions

Rikkunshito reduces fluvoxamine-induced gastrointestinal adverse reactions, especially nausea, without affecting the antidepressant effect of fluvoxamine.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

During the treatment, adverse reactions occurred significantly less frequently in arm 1 (6 patients) than in arm 2 (13 patients). In particular, the frequency of nausea was significantly lower in arm 1 (3 patients) than in arm 2 (9 patients).

11. Abstractor's comments

This paper reports that rikkunshito reduced nausea and other gastrointestinal adverse reactions induced by selective serotonin reuptake inhibitors (SSRI), such as fluvoxamine. Although sample size was relatively small, this trial was well-designed and valuable since it showed the usefulness of Kampo medicines from the perspective of reducing the adverse reactions to western medicines.

12. Abstractor and date

Oikawa T, 31 December 2008, 1 June 2010, 31 December 2013.