

## 6. Nervous System Diseases (including Alzheimer's Disease)

### References

Yakabi K, Yamaguchi N, Ono S, et al. Open label trial of the efficacy and safety profile of rikkunshito used for the treatment of gastrointestinal symptoms in patients with Parkinson's disease: a pilot study. *Current Therapeutic Research* 2017; 87: 1-8. Pubmed ID: 28912900

### 1. Objectives

To evaluate the efficacy and safety of rikkunshito (六君子湯) for anorexia and dyspepsia in patients with Parkinson's disease

### 2. Design

Randomized controlled trial (cross over) (RCT- cross over)

### 3. Setting

One university hospital, Japan

### 4. Participants

Fourteen patients with Parkinson's disease aged between  $\geq 20$  and  $\leq 85$  years, with Hoehn-Yahr stage I to III, and symptoms of anorexia or dyspepsia

Exclusion criteria were intolerance to oral administration of medication, use of drugs that could not be used concomitantly with rikkunshito, current presence of cardiac, hepatic, renal, or hematological disease or malignancy, and history of allergy to Kampo medicines.

### 5. Intervention

Arm 1: TSUMURA Rikkunshito (六君子湯) Extract Granules 7.5 g/day administered orally (2.5 g t.i.d. 4-week treatment, followed by 4-week off treatment) (n=7)

Arm 2: TSUMURA Rikkunshito (六君子湯) Extract Granules 7.5 g/day administered orally (2.5 g t.i.d. 4-week off treatment, followed by 4-week treatment) (n=7)

### 6. Main outcome measures

Primary endpoint was the change in appetite score on a 100-mm visual analog scale (VAS). Secondary endpoints were the changes in gastric emptying, plasma acylated ghrelin level, depression as assessed using the self-rating depression scale (SDS), and gastrointestinal quality of life (QOL) as assessed using the Gastrointestinal Symptom Rating Scale (GSRS).

### 7. Main results

Rikkunshito treatment produced a significant increase in the appetite VAS score (1.84 [2.34]), compared to a decrease in the score over the off-treatment period (-1.36 [2.94]) ( $P=0.041$ ). The SDS score significantly decreased with rikkunshito treatment ( $P=0.026$ ). No effects of rikkunshito were determined on the GSRS score, plasma acylated ghrelin level, or gastric emptying.

### 8. Conclusion

Rikkunshito may improve anorexia in patients with Parkinson's disease.

### 9. From Kampo medicine perspective

None

### 10. Safety assessment in the article

Throughout the study period, no adverse events or abnormal changes were identified with rikkunshito treatment.

### 11. Abstractor's comments

Rikkunshito is known to be effective for gastrointestinal symptoms (anorexia and dyspepsia). Since gastroparesis and constipation commonly occur in patients with Parkinson's disease, this report indicating improvement of anorexia by rikkunshito in Parkinson's disease patients is important. In addition, the study suggested that the positive effects of rikkunshito on depression and anorexia in Parkinson's disease patients may improve their QOL. However, as stated by the authors, the sample size in each arm was limited and did not permit multiple comparisons. Validation of the results using a randomized, double-blind, controlled trial in a larger sample size is awaited.

### 12. Abstractor and date

Kato Y, 1 June 2020.