Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

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

#### Reference

Satoh T, Takahashi T, Iwasaki K, et al. Traditional Chinese Medicine on four patients with Huntington's disease. *Movement Disorders* 2009; 24 453-5.

### 1. Objectives

To evaluate the efficacy and safety of yokukansan (抑肝散) in patients with Huntington's disease.

# 2. Design

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

### 3. Setting

Not mentioned (the first author belongs to the faculty of Yonezawa National Hospital), Japan.

## 4. Participants

Four female patients with Huntington's disease (aged 48, 51, 52, and 68 years).

#### 5. Intervention

- Arm 1: TSUMURA Yokukansan (抑肝散; dose, not specified) Extract Granules for 8 weeks, followed by 4 weeks of wash-out, then TSUMURA Saikokaryukotsuboreito (柴胡加竜骨牡蛎湯; dose, not specified) Extract Granules for 8 weeks (n=2).
- Arm 2: TSUMURA Saikokaryukotsuboreito (柴胡加竜骨牡蛎湯; dose, not specified) Extract Granules for 8 weeks, followed by 4 weeks of wash-out, then TSUMURA Yokukansan (抑肝散; dose, not specified) Extract Granules for 8 weeks (n=2).

#### 6. Main outcome measures

Motor functions, cognitive functions, and activities of daily living were evaluated using the Unified Huntington's Disease Rating Scale - motor assessment (UHDRS-m), Mini-Mental State Examination (MMSE), and Barthel Index, respectively, at the start and end of yokukansan and saikokaryukotsuboreito treatments in both arms.

#### 7. Main results

The UHDRS-m was decreased significantly during yokukansan treatment in all 4 patients (from  $106.3\pm4.7$  to  $89.6\pm5.8$ ; *P*=0.0004), but not significantly during saikokaryukotsuboreito treatment in 3 out of 4 patients (from  $105.5\pm3.8$  to  $101\pm2.9$ ). There were no changes in MMSE and Barthel Index after either treatment.

#### 8. Conclusions

Yokukansan may improve motor function (UHDRS-m score) in patients with Huntington's disease.

**9.** From Kampo medicine perspective None.

#### 10. Safety assessment in the article

There were no abnormal findings in hematology and blood biochemistry after the yokukansan or saikokaryukotsuboreito treatment.

#### 11. Abstractor's comments

In this clinical study, the effects of yokukansan on Huntington's disease, an intractable disease, were objectively evaluated using the UHDRS-m. Videos are also available on this Journal website, thus the article may have a powerful impact on readers. Notably, the authors attempted to evaluate the effects of yokukansan in a cross-over design, despite the difficulties in collecting cases of this rare disease. However, in one of the four participants, improvement was greater during the saikokaryukotsuboreito treatment than during the yokukansan treatment. The results would be more valuable if the data had been analyzed rigorously as a cross-over design. Because there is no established treatment, it might be difficult to have a control group. Yet the use of non-Kampo medicine as a control should be considered. As the authors noted, in the future, a controlled trial with a larger number of patients should be conducted. Still, this study is meaningful in that it provided findings that suggest, albeit hypothetically, the efficacy of yokukansan for this rare disease with no remedy at present.

#### 12. Abstractor and date

Goto H, 1 June 2010, 31 December 2013.