

5. Psychiatric/Behavioral Disorders

Reference

Iwasaki K, Satoh-Nakagawa T, Maruyama M, et al. A randomized, observer-blind, controlled trial of the traditional Chinese medicine yi-gan san for improvement of behavioural and psychological symptoms and activities of daily living in dementia patients. *Journal of Clinical Psychiatry* 2005; 66: 248-52. CENTRAL ID: CN-00502716, Pubmed ID: 15705012

1. Objectives

To evaluate the efficacy and safety of yokukansan (抑肝散) for treating behavioral disorders and improving activities of daily living in dementia patients.

2. Design

Randomized controlled trial (RCT).

3. Setting

Three hospitals (long-term care facilities), Japan.

4. Participants

A total of 60 patients with dementia due to Alzheimer's disease, cerebrovascular disorder, or Lewy body disease, having a Mini-Mental State Examination (MMSE) score of <24 and a neuropsychiatric inventory (NPI) score of >6; of these, 52 patients were included for analysis.

5. Intervention

Arm 1: oral administration of 7.5 g/day of TSUMURA Yokukansan (抑肝散) Extract Granules in 3 divided doses before meals for 4 weeks (n=27).

Arm 2: untreated control group (n=25).

6. Main outcome measures

MMSE score, Barthel Index, and NPI score.

7. Main results

No changes were found in MMSE score in either group. Significant improvements (compared with baseline) were observed in Barthel Index, from 56.4±34.2 to 62.9±35.2, and NPI score, from 37.9±16.1 to 19.5±15.6, in arm 1. In NPI subscales for hallucination, anxiety/excitement, etc., significant improvements over baseline were noted in arm 1. Additional treatment with tiapride hydrochloride, a dopamine D₁ selective neuroleptic, was required in 11 patients in arm 2 but in none in arm 1.

8. Conclusions

Yokukansan is effective for improvement of behavioral disorders and activities of daily living in dementia patients.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Dizziness and impaired postural sway were reported in 6 patients (54.5%) treated with tiapride hydrochloride. Two patients (7.4%) who continued yokukansan after the end of the observation period became oversedated but recovered with a reduced dose.

11. Abstractor's comments

This study, which investigated the efficacy of yokukansan for cognitive function and activities of daily living in elderly dementia patients in an RCT, provides high-quality evidence. However, the same nurses who rated MMSE and NPI scores, and Barthel Index may also have administered yokukansan, suggesting the possibility of a lack of blinding, which may have affected evaluations. In future, the effects of yokukansan in dementia patients are expected to be studied over a longer term.

12. Abstractor and date

Goto H, 15 June 2007, 1 April 2008, 1 June 2010.