5. Psychiatric/Behavioral Disorders

Reference

Iwasaki K, Kanbayashi S, Chimura Y, et al. A randomized, double-blind, placebo-controlled clinical trial of the Chinese herbal medicine "ba wei di huang wan" in the treatment of dementia. *Journal of the American Geriatrics Society* 2004; 52: 1518-21. CENTRAL ID: CN-00491098, Pubmed ID: 15341554

1. Objectives

To evaluate the efficacy of hachimijiogan (八味地黄丸) for dementia.

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

Single hospital (long-term care facility), Japan.

4. Participants

Thirty-three anticholinergic-untreated dementia patients with an MMSE score of 0 – 25.

5. Intervention

Arm 1: oral administration of Uchida Hachimijiogan (八味地黄丸) 2.0g t.i.d. after meals for 8 weeks (n=16).

Arm 2: oral administration of 2.0 g of honey-mixed black rice powder as placebo t.i.d.after meals for 8 weeks (n=17).

6. Main outcome measures

Mini-Mental State Examination (MMSE) score, Barthel Index, and internal carotid artery pulsatility index at baseline, 8 weeks after start of dosing, and 8 weeks after completion of dosing.

7. Main results

After 8 weeks of dosing, in arm 1, a significant improvement over baseline was observed in MMSE score, from 13.5±8.5 to 16.3±7.7, Barthel Index, from 61.8±34.6 to 78.9±21.1, and pulsatility index, from 2.5±1.7 to 1.9±0.5, whereas no changes were noted in these variables in arm 2. At 8 weeks after completion of dosing (16 weeks after start of dosing), MMSE score and Barthel Index of arm 1 returned to control (arm 2) levels.

8. Conclusions

Hachimijiogan improves cognitive function, activities of daily living, and internal carotid arterial blood flow in dementia patients.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

During the study period, no adverse drug reactions occurred in either group. After completion of dosing, a hospital change due for personal reasons, and urinary tract infections and upper respiratory tract infections occurred in 1 and 2 patients in arm 1, respectively.

11. Abstractor's comments

This study, which investigated the efficacy of hachimijiogan for preserving or restoring cognitive function and activities of daily living in elderly dementia patients in a double-blind RCT, provides high-quality evidence. At week 16, MMSE scores of the hachimijiogan group had a large standard deviation (SD), indicating wide inter-individual variation in dementia severity. Even in the placebo group, MMSE score and Barthel Index did not worsen, though the study population included patients with Alzheimer's disease, suggesting disease progression may have been slower in these very old patients (aged 83 to 85 years, on average). In addition, whether the hachimijiogan-induced improvement (a mean of 2.8 points) in the dementia score of the MMSE led to clinical improvement will require further investigation. It is recommended that investigation separate patients with cerebrovascular disorders from those with Alzheimer's disease. To further elucidate the efficacy of hachimijiogan, longer-term observation of a larger sample is expected.

12. Abstractor and date

Goto H, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.