

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

Reference

Sekine R, Watanabe H, Mimura M, et al. The effects of gosha-jinki-gan on the low back pain and lower limb pain caused by the lumbar spine: A comparison of Gosha-jinki-gan with Benfotiamine. *Itami to Kampo (Pain and Kampo Medicine)* 2003; 13: 84-7 (in Japanese with English abstract). Ichushi Web ID: 2006247217

1. Objectives

To evaluate the efficacy of goshajinkigan (牛車腎気丸) for treatment of lumbar (low back) and leg pain.

2. Design

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

3. Setting

One general hospital and one university hospital, Japan.

4. Participants

Twenty patients with lumbar degeneration (aged 60 years or older) with a chief complaint of low back and leg pain persisting over 6 months.

5. Intervention

Arm 1: oral administration of 7.5 g/day of goshajinkigan (牛車腎気丸) extract granules for 4 weeks, followed by oral administration of 75 mg/day of benfotiamine for 4 weeks (n=10).

Arm 2: oral administration of 75 mg/day of benfotiamine for 4 weeks, followed by oral administration of 7.5 g/day of goshajinkigan (牛車腎気丸) extract granules for 4 weeks (n=10).

In each group, one patient experienced gastrointestinal symptoms following administration of goshajinkigan (牛車腎気丸) and was excluded from the statistical analysis.

6. Main outcome measures

Subjective symptoms (low back pain at rest, low back pain with motion, leg pain at rest, leg pain with motion, leg numbness, and leg fatigue), and clinical laboratory tests (hematology, blood biochemistry, and urinalysis).

7. Main results

Subjective symptoms – low back pain at rest, low back pain with motion, and leg numbness – were significantly improved after administration of goshajinkigan, compared with benfotiamine.

8. Conclusions

Goshajinkigan is more effective than benfotiamine, a vitamin B1 derivative, in the treatment of lumbar (low back) and leg pain.

9. From Kampo medicine perspective

In each arm, 6 patients with *jinkyō* (腎虚, kidney deficiency) were included. No difference was observed in the efficacy between patients with and without *jinkyō*.

10. Safety assessment in the article

Of 20 patients receiving goshajinkigan, 2 experienced gastrointestinal symptoms, which led to discontinuation of treatment. Hematology/biochemistry tests and urinalysis revealed no abnormalities in either arm.

11. Abstractor's comments

This study suggests the efficacy of goshajinkigan for low back and leg pain. To confirm that efficacy is not influenced by the presence of *jinkyō*, a clinical trial with a larger sample size is recommended.

12. Abstractor and date

Kogure T, 15 June 2007, 1 April 2008, 1 June 2010.