

8. Ear Diseases

Reference

Onishi S. Kampo treatment for tinnitus and hearing impairment*. *JOHNS* 1990; 6: 535-9 (in Japanese).

1. Objectives

To evaluate the efficacy and safety of goshajinkigan (牛車腎気丸) for tinnitus.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

Otolaryngology Department, Kanto Teishin Hospital, Japan.

4. Participants

Thirty-nine patients who presented with tinnitus as their chief complaint (22 males and 17 females, age ranging from the 20s to 80s).

5. Intervention

Arm 1: goshajinkigan group. TSUMURA Goshajinkigan (牛車腎気丸) Extract Granules (7.5 g/day) for 8 weeks (n=22).

Eight participants from arm 2 were included in arm 1 for a total of 30 after experiencing no effect from treatment in arm 2.

Arm 2: chotosan group. TSUMURA Chotosan (釣藤散) Extract Granules (7.5 g/day) for 8 weeks (n=24).

Six participants from arm 1 were included in arm 2 for a total of 30 after experiencing no effect from treatment in arm 1.

Participants were allocated to arm 1 or arm 2 in the order of presentation, regardless of their Kampo pattern.

6. Main outcome measures

Tinnitus severity, duration, and how it becomes concerning classified into five grades: remarkable improvement, improvement, slight improvement, no change, and deterioration.

7. Main results

Although there was no significant difference between groups, effectiveness of goshajinkigan for tinnitus tended to be greater (50% with grade 'improvement' or better) than that of chotosan (30% with grade 'improvement' or better). Three out of seven participants with tinnitus following sudden hearing loss in arm 1 and one of the five such participants in arm 2 scored 'improvement' or better. In both groups, most patients experienced an effect within two months of the start of treatment.

8. Conclusions

Goshajinkigan may be effective for tinnitus. Its efficacy is at least equivalent to chotosan.

9. From Kampo medicine perspective

While the Kampo medications were administered regardless of the patient's Kampo pattern, tinnitus is a major symptom within the goshajinkigan-pattern (by stratified analysis), and no relation between effectiveness and the existence of lower limb pain, numbness, and swelling could be identified.

10. Safety assessment in the article

Diarrhea was observed in one participant in each group, however it was not severe enough to discontinue administration.

11. Abstractor's comments

This is a clinically significant study in that it compared and analyzed the clinical effects of goshajinkigan for tinnitus to those of chotosan in a controlled clinical trial. Its clinical significance would be improved by analyzing effectiveness in patients administered goshajinkigan and chotosan in a crossover manner with a required washout period after demonstrating ineffectiveness in each group. Further research is anticipated.

12. Abstractor and date

Kogure T, 31 December 2013.