

8. Ear Diseases

Reference

Tanaka H. Efficacy of a Kampo preparation combined with tranquilizers in patients with tinnitus. *Jibiinkoka Rinsho (Practica otologica)* 1996; suppl 89: 8 (in Japanese).

1. Objectives

To evaluate the efficacy of saireito (柴苓湯) combined with tranquilizers for tinnitus.

2. Design

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

3. Setting

Single institution (Department of Otorhinolaryngology, Koseiren Nagaoka Chuo General Hospital), Japan.

4. Participants

Two hundred and twelve tinnitus patients with symptoms of Eustachian tube dysfunction. (The paper mentions 212 participants, however, there are 222 in arms 1 and 2 combined.)

Inclusion criteria were: tinnitus that is 1) worsened by the common cold, nasal allergy, or sinusitis; 2) relieved by Eustachian tube insufflation; 3) still present after myringotomy for otitis media with effusion; 4) complicated by chronic otitis media and relieved by the patch test; or 5) associated with sequelae of otitis media.

5. Intervention

Arm 1: treatment with tranquilizer alone for more than 4 weeks, then combined with Kanebo Saireito (柴苓湯) Extract Fine Granules (n=104).

Arm 2: treatment with Kanebo Saireito (柴苓湯) Extract Fine Granules + tranquilizer combination for 2 weeks, then tranquilizer alone (n=118).

6. Main outcome measures

Changes in the symptoms (measured using a 3-point scale corresponding to improvement, no change, and worsening).

7. Main results

Efficacy was observed in around 60% of patients treated with the combination (69/104 in arm 1 and 58/118 in arm 2) and in 62.6% and 57.1% of patients treated with 8.1 g and 5.4 g of saireito, respectively. Even the lower-dose administration was effective.

8. Conclusions

Saireito combined with tranquilizers was effective for treating tinnitus. Current Kampo extract preparations contain large amounts of ingredients. Considering the possibility of poor drug compliance, the treatment with 5.4 g of saireito was suggested to be useful.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This study was referred to as a RCT-cross over study, based on the mention of "cross-over trial" in the paper. But it was a short paper and information was scarce. Basic information, including age and sex of participants, names of tranquilizers used, and when, how, and by whom the outcomes were measured, is absent and therefore assessment of this study is difficult. The development of future studies on this topic is expected.

12. Abstractor and date

Tsuruoka K, 22 April 2008, 1 June 2010, 31 December 2013.