8. Ear Diseases

Reference

Ino T, Odaguchi H, Wakasugi A, et al. A randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy of hangekobokuto in adult patients with chronic tinnitus. *Journal of Traditional Medicines* 2013; 30: 72-81. Ichushi Web ID: 2013310385 J-STAGE

1. Objectives

To evaluate the effects of hangekobokuto (半夏厚朴湯) on chronic tinnitus.

2. Design

Double-blind, placebo-controlled, randomized controlled trial (DB-RCT).

3. Setting

Department of Otorhinolaryngology, Kitasato University Hospital, Japan.

4. Participants

Seventy-six adults aged at least 20 years with tinnitus persisting for at least three months, the impairment rated at least 18 points on the Tinnitus Handicap Inventory score (THI score), or between mild and severe. The five exclusion criteria were: (1) objective tinnitus, intermittent tinnitus, or pulsatile tinnitus; (2) conductive hearing impairment; (3) acoustic nerve tumor confirmed by MRI or clinically related nerve impairment, psychiatric disorder, or systemic disease (e.g. cardiac disease, malignant tumor, renal failure, hepatic failure); (4) administration of a Kampo medication within 4 weeks before the trial; and (5) currently pregnant or breastfeeding.

5. Intervention

Arm 1: Kracie Hangekobokuto (半夏厚朴湯) Extract Tablets, 6 tablets b.i.d. for 12 weeks (n=38)

Arm 2: Placebo, 6 tablets b.i.d. for 12 weeks (n=38). The placebo tablets were made of cornstarch and lactose to resemble the Hangekobokuto (半夏厚朴湯) Extract Tablets in color, form, weight, smell and taste.

6. Main outcome measures

The main outcome was the difference between baseline and final THI scores. Secondary outcomes: changes in the visual analog scale (VAS), Hospital Anxiety and Depression Scale (HADS), and Short-Form 36-Items Health Survey scores (SF36).

7. Main results

There was no significant difference between arms in THI scores (total: P =0.73, functional: P=0.99, emotional: P=0.78, catastrophic: P=0.59). There was no significant difference in the secondary outcome measures. There was no difference between arms in THI score among participants with no anxiety or depression. THI scores tended to improve in the hangekobokuto arm compared to the placebo arm among participants with dizziness (total: P=0.006). The authors did a hangekobokuto pattern subgroup analysis (16 participants in the hangekobokuto arm and 26 in the placebo arm), but there was no significant difference between groups.

8. Conclusions

While there were no significant differences between arms, hangekobokuto tended to improve THI scores for participants with dizziness more than the placebo.

9. From Kampo medicine perspective

As mentioned in the results, a hangekobokuto pattern subgroup analysis was carried out.

10. Safety assessment in the article

Itchiness and worsened tinnitus were observed in the placebo arm. Neither was sufficiently severe to discontinue the trial.

11. Abstractor's comments

This is a well-designed RCT. The randomization, delineation between the inclusion and exclusion criteria, participant recruitment, flow diagram, and outcomes were clear and readily comprehensible. It is an exemplary paper with much to teach new learners of EBM. Although unfortunately the results did not demonstrate significant differences, as the authors mention in their considerations, they will take the next step forward by finding the definitive factors that lead to Kampo medication prescribing, and formulating a study design that fully reflects the particular features of Kampo. Further development of this research is anticipated.

12. Abstractor and date

Tsuruoka K, 6 June 2015.