

8. Ear Diseases

Reference

Kaneko T. Comparison of saireito and isosorbide in efficacy against low-frequency sensorineural hearing loss. *Kampo to Saishin Chiryō (Kampo and the Newest Therapy)* 2010; 19: 233–9 (in Japanese with English abstract). Ichushi Web ID: 2010304850

1. Objectives

To compare the effectiveness of saireito (柴苓湯) and isosorbide for low-frequency sensorineural hearing loss.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

An otorhinolaryngology clinic (Tochigi prefecture), Japan

4. Participants

One hundred and fifty-five patients with low-frequency sensorineural hearing loss who presented with ear blockage sensation as chief complaint between June 2008 and October 2009.

5. Intervention

Arm 1: TSUMURA Saireito (柴苓湯) Extract Granules 3.0 g t.i.d. (n= 76).

Arm 2: isosorbide (Kowa Pharmaceutical Co., Ltd., Isobide) 30 mL t.i.d. (n=75).

6. Main outcome measures

Two measures: pure tone audiometry and subjective symptoms. Assessment by pure tone audiometry was divided into four stages: recovered (hearing threshold levels for three low frequencies [125, 250, and 500 Hz] all found within 20 dB, or no left/right difference detected), improvement (restored to 10 dB or more, but not full recovery), no change (less than 10 dB), and worsening. Four-stage subjective assessment: improved, somewhat improved, no change, worsened.

7. Main results

The number of tested patients was 51 in arm 1 (10 males and 41 females; ages 19–76; mean age 47.8 years) and 53 in arm 2 (16 males and 37 females; ages 11–78; mean age 47.1 years). Arm 1 showed a slightly stronger tendency for improvement in the hearing test compared to arm 2, but no statistically significant difference was observed. The subjective measures “no change” and “worsened” tended to be more common in arm 2, but no significant difference was observed. Comparison of initial occurrences with recurrences showed that improvement tended to be more difficult after recurrence in both groups, but no significant difference was observed. Recovery tended to be poor in subjects with dizziness symptoms in both groups, but no significant difference was observed.

8. Conclusions

Saireito and isosorbide are similarly effective for low-frequency sensorineural hearing loss.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor’s comments

Low-frequency sensorineural hearing loss is frequently encountered in daily practice, nevertheless, its causes remain unknown. A finding of the study that is significant in clinical and pathological terms is that Saireito and isosorbide have equal effectiveness. Unfortunately, the trial amounted to a quasi-RCT because allocation of participants to receive one of the treatments was in the order of diagnosis. The reliability of the results could have been improved if patients who did not return to the clinic for determination of the effects of treatment could have been followed up. Participants might not have returned because their symptoms improved or because they visited another clinic. This greatly affected the results. Hopefully the researcher will properly randomize the trial and improve the follow-up rate in the next stage of his research. In this study a doctor at the frontline of community health care has attempted an RCT to verify a medical practice that has concerned him in the clinic. It is praiseworthy for its contribution to the development of Kampo medicine.

12. Abstractor and date

Tsuruoka K, 31 December 2012.