

8. Ear Diseases**Reference**

Yoshizaki T. A multicenter, double-blind, randomized controlled trial on the usefulness of juzentaihoto in children with recurrent otitis media* (2009-clinical study-general—007) *Chozai to Joho (Dispensing and Information)* Health Labour Sciences Research Grant, General Research Program for Practical Application of Medical Technology, 2009, General Research Report in 2011. 2012: 1-23 (in Japanese).

1. Objectives

To evaluate the efficacy and safety of juzentaihoto (十全大補湯) in children with recurrent otitis media.

2. Design

Randomized controlled trial (RCT).

3. Setting

Seven university hospitals, 8 hospitals, and 11 otorhinolaryngological clinics, Japan.

4. Participants

Eighty-seven children aged \geq six months and <4 years with otitis media, recurrences of otitis media that were difficult to treat with standard therapy, a diagnosis of recurrent otitis media "acute otitis media occurring three times or more within the past 6 months, or four times or more within the past 12 months," and any of the following symptoms: a decrease in physical strength, fatigue and malaise, anorexia, night sweat, cold extremities, or anemia.

5. Intervention

Arm 1: Juzentaihoto (十全大補湯) (manufacturer unknown) administered orally at 0.05 to 0.125 g/kg b.i.d and standard therapy for 3 months (n=39).

Arm 2: Standard therapy alone (n=48).

6. Main outcome measures

The mean number of recurrences with acute otitis media per month during the study, and the difference in mean number of recurrences with acute otitis media per month between baseline and endpoint of the study, mean number of recurrences with coryza per month, mean frequency of antibiotic use per month, number of subjects treated by eardrum ventilation tube insertion during the study, general condition including nutritional status (e.g., albumin level at the completion of the study, Kaup's index), and anemia improvement (yes or no).

7. Main results

A total of 70 subjects were included in the analysis: 31 subjects in the juzentaihoto arm and 39 subjects in the standard therapy alone arm. Compared with Arm-2 patients, Arm-1 patients had decreased mean number of recurrence with acute otitis media per month (time/month) and coryza per month, and decreased mean frequency of antibiotic use per month. However, there was no significant inter-arm difference in nutritional status or anemia improvement.

8. Conclusions

Juzentaihoto decreases the incidence of recurrent otitis media in children.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

One subject in the juzentaihoto arm experienced skin rash, leading to suspension of treatment. No significant inter-arm difference in blood chemistry was found throughout the study.

11. Abstractor's comments

This clinical study, which evaluated the efficacy of juzentaihoto in pediatric patients with recurrent otitis media, a widely prevalent and refractory disease, is highly valuable with regard to clinical significance, setting, and study methods. However, this study was published as a report, many details of the results were not mentioned. A more detailed presentation of the results should be published. As stated by the authors, more evidence of juzentaihoto's efficacy in the treatment of childhood recurrent otitis media is desired and will be sought in the future.

12. Abstractor and date

Goto H, 31 March 2017.