

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).

Ito M, Maruyama Y, Kitamura K, et al. Randomized controlled trial of juven-taiho-to in children with recurrent acute otitis media *Auris Nasus Larynx* 2017; 44: 390-7. Ichushi Web ID: 2018007858, Pubmed ID: 278101268

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

Primary outcome: The mean number of recurrences with acute otitis media per month during the study.

Secondary outcome: The 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 and the period of treatment.

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. For the primary outcome, a significant decrease in the mean number of acute otitis media recurrences was observed in Arm 1 (0.61 ± 0.54 recurrences/month) compared to Arm 2 (1.07 ± 0.72 recurrences/month) ($P=0.005$). For the secondary outcomes, significant improvements were observed for both the mean number of coryza recurrences per month and the mean frequency of antibiotic use per month ($P=0.015$, $P=0.024$) in Arm 1 compared to Arm 2.

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. Initially the study was presented in the form of a report, but in 2017 the details were clearly described and was published as a research paper. The report issued in 2012 mentioned that juzentaihoto showed efficacy in the subjects showing indications of "decreased physical strength after illness, fatigue, loss of appetite, night sweats, coldness in the extremities, and anemia". Furthermore, the authors also investigated overall physical condition, including nutritional status and whether or not there was any improvement in anemia, and reported that there was no difference between the Arms. As the authors mentioned, this clinical research is fully expected to generate evidence for the efficacy of juzentaihoto in the treatment of childhood recurrent otitis media in the future.

12. Abstractor and date

Goto H, 31 March 2017, 1 June 2020.