

10. Respiratory Diseases (including Influenza and Rhinitis)**Reference**

Saiki I, Koizumi K, Goto H, et al. The long-term effects of a Kampo medicine, juzentaihoto, on maintenance of antibody titer in elderly people after influenza vaccination. *Evidence-Based Complementary and Alternative Medicine* 2013; 1-8. doi: 10.1155/2013/568074. Pubmed ID: 24348705

1. Objectives

To evaluate the long-term effects of juzentaihoto (十全大補湯) on maintenance of the anti-influenza antibody titer in elderly people after influenza vaccination.

2. Design

Randomized controlled trial (RCT).

3. Setting

Four long-term care facilities, Japan.

4. Participants

Ninety patients aged 65 years or older who were receiving long-term care for cerebrovascular disease, dementia, bone, joint disease, etc.

5. Intervention

Arm 1: Kracie Juzentaihoto (十全大補湯) Extract Granules administered orally or through a gastrostomy tube 3.75 g b.i.d. for a total of 28 weeks (i.e., from 4 weeks before influenza vaccination to 24 weeks after influenza vaccination) (n=44).

Arm 2: No administration (n=46).

6. Main outcome measures

Antibody titer to influenza virus A (H1N1 and H3N2) and B at Weeks -4, 0, 4, 8, 12, and 24.

7. Main results

The H3N2 antibody titer was significantly higher in the juzentaihoto arm (Arm 1) than in the control arm (Arm 2) at 8 weeks after vaccination ($P=0.0229$), and rose still higher at Weeks 4, 12, and 24. In addition, the antibody titer from Weeks 4 to 24 was significantly higher in Arm 1 than in Arm 2 ($P=0.0468$). There was no significant inter-arm difference in antibody titers to H1N1 or B at any post-vaccination week.

8. Conclusions

Juzentaihoto increases and maintains the titer of influenza antibodies especially those specific for H3N2.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Epigastric discomfort was reported in one subject after administration of juzentaihoto, but improved after discontinuation of administration. There were no significant changes in serum chemistry values in the two arms.

11. Abstractor's comments

Notably, this RCT demonstrated significantly higher anti-H3N2 antibody titers at Week 8 after vaccination in elderly people, at high risk for influenza infection, treated with juzentaihoto from 4 weeks before to 24 weeks after vaccination, a total of 28 weeks. Although a previous RCT of maobushisaishinto had reported that anti-H3N2 antibody titers were significantly higher at Week 4, it did not report this effect after Week 4. In another RCT, hochuekkito did not significantly increase antibody titer. These preceding studies and the present study differed in the Kampo products selected, treatment period, target subjects, etc. Especially, the present study included subjects with the mean age of 85.6 years who had experienced the outbreaks of H3N2 in 1968 to 1969, which elicited a strong post-vaccination response. Previously, the adjuvanticity of juzentaihoto was demonstrated in a basic study. This is the first RCT to clinically evaluate the effect of juzentaihoto on enhancing production of influenza antibody.

12. Abstractor and date

Motoo Y, 31 March 2017.