

21. Others

Reference

Hamazaki K, Sawazaki S, Itomura M, et al. No effect of a traditional Chinese medicine, hochu-ekki-to, on antibody titer after influenza vaccination in man: a randomized, placebo-controlled, double-blind trial. *Phytomedicine* 2007; 14: 11-4. CENTRAL ID: CN-00576087, Pubmed ID: 16644196

1. Objectives

To assess the efficacy and safety of hochuekkito (補中益気湯) on antibody production after influenza vaccination.

2. Design

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

3. Setting

No description of the setting is available; the authors belong to the Division of Clinical Application, Institute of Natural Medicine, University of Toyama, Japan.

4. Participants

Of the 49 healthy males aged between 20 and 60 years who volunteered to enter this trial of hochuekkito, 36 were enrolled. None of the 36 had been taking any herbal medicine, hormone therapy, or anti-inflammatory drugs.

5. Intervention

Arm 1: administration of Kanebo Hochuekkito (補中益気湯) Extract Fine Granules 3.75 g b.i.d. before breakfast and supper for 14 days until the day prior to influenza vaccination, n=18.

Arm 2: administration of placebo (consisted mainly of cane sugar) 3.75 g b.i.d. before breakfast and supper for 14 days until the day prior to influenza vaccination, n=18.

6. Main outcome measures

Blood samples were taken at weeks 0, 1, 2, 4, and 12. Hemagglutination inhibition (HI) was used to measure influenza antibody titer, and a chromium (Cr)-release assay was used to measure natural killer (NK) activity.

7. Main results

Three subjects in arm 2 (because of common cold and diarrhea) and one subject in arm 1 (for a personal reason) dropped out of the study. There were no significant between-arm differences in postvaccination titer and NK activity.

8. Conclusions

Oral administration of hochuekkito for 14 days before influenza vaccination does not affect postvaccination antibody production.

9. From Kampo medicine perspective

Subjects not intending to use hochuekkito, as well as subjects with easy fatigability, a high susceptibility to colds, slow recovery from colds, a high susceptibility to other infections like herpes and wound infection, poor appetite, loose bowels, and somnolence especially after meals, were excluded from the study.

10. Safety assessment in the article

No adverse effects were observed.

11. Abstractor's comments

This is a high-quality, well-designed, and double-blind clinical trial to assess the effect of hochuekkito on antibody production after influenza vaccination. A similar report (Yamaguchi H et al., Assessment of the effect of hochuekkito extract on antibody response to influenza vaccination. *Kampo to Saishin-chiryō [Kampo & the Newest Therapy]* 2006; 15: 235-7 [in Japanese]) concluded similarly that oral administration of hochuekkito for 1 week after the vaccination has no effect on antibody production. On the other hand, as mentioned in the discussion of this paper, Takagi et al. reported that hochuekkito increased antibody production in old mice (Takagi et al. Antibody response of Kampo-hozai after influenza B immunization in old mice. *The Japanese Society for Vaccinology* 2002; 6: 72 [abstract in Japanese]). Considering that all the clinical trials were conducted with healthy subjects, further investigation in the elderly with decreased ability to produce antibodies is awaited. The design of this clinical trial, based on the result from basic studies, should be emulated by researchers who conduct clinical trials of Kampo medicines.

12. Abstractor and date

Goto H, 21 November 2008, 1 June 2010.