Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

#### 21. Others Reference

Terashima Y, Hamazaki K, Itomura M, et al. Effect of a traditional Chinese medicine, maobushisaishinto, on the antibody titer after influenza vaccination: A randomized, placebo-controlled, double-blind trial. *Journal of Traditional Medicines* 2007; 24: 59-66. Ichushi Web ID: 2007258196 J-STAGE

# 1. Objectives

To evaluate the effect of maobushisaishinto (麻黄附子細辛湯) on antibody titer after influenza vaccination.

# 2. Design

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

#### 3. Setting

Two university hospitals, Japan.

#### 4. Participants

One hundred and six healthy subjects aged 20–71 years.

#### 5. Intervention

Maobushisaishinto (麻黄附子細辛湯) and placebo capsules were donated by Kotaro Pharmaceutical Co., Ltd. The following drugs were orally administered from day –14 to –1 of influenza vaccination (A/H1N1, A/H3N2, B). All subjects were vaccinated in late November, before the influenza season. Arm 1: Kotaro Maobushisaishinto (麻黄附子細辛湯) Extract Capsules (6 capsules/day), n=23. Arm 2: placebo capsules, n=24.

#### 6. Main outcome measures

Serum hemagglutination inhibition titers were measured at weeks 0, 1, 2, 4, and 12.

# 7. Main results

After excluding 57 subjects with antibody titers of more than 1:80 and 2 subjects diagnosed with influenza during the study period (one in each arm), 23 and 24 subjects were enrolled for analysis. There was no significant between-arm difference in antibody titer against A/New Caledonia/20/99(H1N1), A/New York/55/2004(H3N2), and B/Shanghai/361/2002. However, anti-H3N2 virus antibody titer was significantly higher in arm 2 than in arm 1 at week 4. Subgroup comparisons (smokers *vs* non-smokers and older subjects [ $\geq$ 40 years old] *vs* younger subjects [<40 years old]) found no significant between-arm differences in antibody titers.

# 8. Conclusions

No adjuvant effect of maobushisaishinto on antibody titer after influenza vaccination is observed.

# 9. From Kampo medicine perspective

None.

# **10.** Safety assessment in the article Not documented.

#### 11. Abstractor's comments

Previous studies have shown the adjuvant effect of maobushisaishinto on influenza vaccination in animals and in elderly subjects. This paper aims to verify this effect.

# 12. Abstractor and date

Fujisawa M, 15 January 2009, 1 June 2010.