

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

Iwasaki K, Taguchi M, Cyong JC, et al. Effect of mao-bushi-saishin-to on influenza vaccination in elderly subjects: a randomized controlled study. *Kampo to Meneki-Arerugi (Kampo and Immuno-Allergy)* 2004; 17: 97-103 (in Japanese with English abstract).

Iwasaki K. Influenza and Kampo in the elderly\*. *TSUMURA Mail Magazine* 2008; Suppl: 22-3 (in Japanese).

**1. Objectives**

To evaluate the efficacy and safety of maobushisaishinto (麻黄附子細辛湯) as an adjuvant for influenza vaccination in the elderly.

**2. Design**

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

**3. Setting**

Not documented, Japan.

**4. Participants**

Eighteen patients with antibody titers of <1:10 to two types of influenza A antigens (H1N1, H3N2) as measured using an hemagglutination inhibition (HI) assay.

**5. Intervention**

Arm 1: oral administration of TSUMURA Maobushisaishinto (麻黄附子細辛湯) Extract Granules ([TJ-127]), 7.5 g/day, from 7 days before influenza vaccination until 14 days after vaccination; n=10.

Arm 2: no administration of TJ-127; influenza vaccination only; n=8.

**6. Main outcome measures**

Rise in antibody titer from baseline was measured at 4 weeks after vaccination and the rate of rise was compared between arms.

**7. Main results**

There was no significant between-arm difference in anti-H1N1 antibody titer. Anti-H3N2 antibody titer increased on average 4.9-fold in arm 2 (when compared with baseline) and 57.3-fold in arm 1 which was significant ( $P<0.04$ ) when compared with arm 2. During the observation period, 2 patients in arm 2 but none in arm 1 became infected with influenza A virus.

**8. Conclusions**

The rise in anti-H3N2 antibody titer (but not anti-H1N1 antibody titer) was significantly greater in arm 1 than arm 2, suggesting that maobushisaishinto enhances the anti-H3N2 antibody titer induced by influenza vaccination and enhances specific immunity.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not documented.

**11. Abstractor's comments**

Influenza infection complicated with infections such as pneumonia contributes substantially to mortality in the elderly. Therefore, boosting the production of anti-influenza virus antibody would have an important preventive effect and reduce the cost of influenza treatment. From these points of view, this study investigated whether administration of maobushisaishinto can increase antibody level, with the expectation that maobushisaishinto acts as an adjuvant of the humoral immune response in the elderly with low influenza-antibody level. This report focuses on strategies for the prevention of influenza in the elderly with low response to influenza vaccine. Further studies are needed to determine why only anti-H3N2 antibody titer is significantly increased compared with control group whereas no significant difference was observed in anti-H1N1 antibody, and whether maobushisaishinto can promote production of specific antibodies.

The small number of patients was a problem in this study. Further analyses with an increased number of cases are necessary. Also studies on other Kampo medicines with adjuvant effects in subjects with low antibody production against influenza virus, and on methods of administration, are awaited.

Iwasaki (2008) reported that the number of the participants is higher, i.e., 18 in arm 1 (the maobushisaishinto group) and 15 in arm 2 (the control group). The results were almost the same, revealing elevated anti-H3N2 antibody titer in arm 1.

**12. Abstractor and date**

Namiki T, 15 June 2007, 1 April 2008, 12 March 2009, 1 June 2010, 31 December 2013.