

## 21. Others

### Reference

Ogawa H, Xu F, Uebaba K, et al. Antioxidative potentiality of a Kampo formulation measured by an ex vivo study. *The Journal of Alternative and Complementary Medicine* 2009; 15: 267–74.

#### 1. Objectives

To evaluate the antioxidative effect of bofutsushosan (防風通聖散) in healthy adults using the lag time of low-density lipoprotein (LDL) oxidation as the main yardstick.

#### 2. Design

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

#### 3. Setting

University of Toyama, Japan.

#### 4. Participants

Eighteen healthy males (aged 22±3 years) selected from 38 males. The inclusion criteria were total cholesterol ≥180 and ≤220 mg/dL, triglyceride ≤170 mg/dL, high-density lipoprotein (HDL) cholesterol ≥40 mg/dL, LDL cholesterol ≤140 mg/dL. The subjects were randomly assigned to the following three arms.

#### 5. Intervention

Arm 1: bofutsushosan (防風通聖散; Kanebo) 7.5 g/day.

Arm 2: placebo of bofutsushosan (防風通聖散; Kanebo) 7.5 g/day.

Arm 3: tablet containing a mixture of vitamin E (500 mg/day) and vitamin C (1000 mg/day).

#### 6. Main outcome measures

Inhibitory effect on LDL oxidation induced by 2,2'-azobis (4-methoxy-2,4-dimethyl-valeronitrile); the lag time to oxidation (production of conjugated dienes), as a measure of antioxidative effect; plasma ephedrine, plasma baicalin, serum lipid peroxide, serum free fatty acids, urinary 8(OH)dG/creatinine levels, blood pressure, and heart rate.

#### 7. Main results

The lag time tended to be longer, though not significantly longer, in arm 1 than arm 2 ( $P=0.08$ ). There were no significant changes in levels of urinary 8(OH)dG/creatinine and serum lipid peroxide. In arm 1, a sympathomimetic response to the pharmacological action of ephedrine was observed.

#### 8. Conclusions

Although not confirmed, the systemic antioxidative effect of bofutsushosan is suggested by this study.

#### 9. From Kampo medicine perspective

None.

#### 10. Safety assessment in the article

Not mentioned.

#### 11. Abstractor's comments

This double-blind randomized controlled trial (DB-RCT) demonstrated the potential antioxidative effect of bofutsushosan on lipids. Drug administration in arms 1 and 2 was double-blinded, whereas it was unblinded in arm 3. So the study is an incomplete DB-RCT. Yet the outcomes are clinically highly suggestive. In the future, RCTs that involve patients with hyperlipidemia, compare Kampo medicines with standard medications, and use true endpoints to assess outcome are expected to be conducted.

#### 12. Abstractor and date

Tsuruoka K, 1 June 2010.