

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

**Mukaida K, Hattori N, Kondo K, et al. A pilot study of the multiherb Kampo medicine bakumondoto for cough in patients with chronic obstructive pulmonary disease. *Phytomedicine* 2011; 18: 625–9. CENTRAL ID: CN-00790726, Pubmed ID: 21177084**

Hattori N, Mukaida K, Haruta Y, et al. A pilot study of the effects of Bakumondoto (TJ-29) on cough in chronic obstructive pulmonary disease (COPD)\*. *Kampo to Meneki – Arerugi (Kampo and Immuno-Allergy)* 2011; 24: 38–45 (in Japanese with English abstract).

**1. Objectives**

To evaluate the effect of bakumondoto (麦門冬湯) on cough in patients with chronic obstructive pulmonary disease (COPD).

**2. Design**

Crossover randomized controlled trial (RCT –cross over).

**3. Setting**

Hiroshima University Hospital and two general hospitals, Japan.

**4. Participants**

Twenty-four COPD outpatients aged over 65 who presented between May 2007 and March 2009.

**5. Intervention**

Treatment with or without bakumondoto (麦門冬湯) for 8 weeks in a cross-over design.

Patients taking any Kampo medicine within the previous 2 weeks were excluded. Treatment with the usual COPD drugs was continued during the trial.

Arm 1: TSUMURA Bakumondoto (麦門冬湯) Extract Granules 3.0 g t.i.d. before meals for 8 weeks, then no bakumondoto (麦門冬湯) for 8 weeks (n=13).

Arm 2: No bakumondoto (麦門冬湯) for 8 weeks, then TSUMURA Bakumondoto (麦門冬湯) Extract Granules 3.0 g t.i.d. before meals for 8 weeks (n=11).

One subject in arm 1 was excluded from the efficacy analysis.

**6. Main outcome measures**

Frequency and intensity of cough assessed on a VAS (visual analogue scale) and changes in severity as recorded in a cough diary. Quality of life (QOL) using St. George's Respiratory Questionnaire (SGRQ). Lung functions.

**7. Main results**

Twenty-three patients were included in the efficacy analysis. VAS scores showed significant improvement in cough intensity and frequency during the first 8-week period of treatment with bakumondoto in arm 1 ( $P=0.004$ ), but the magnitude of improvement gradually declined after treatment ceased. In arm 2, however, no significant improvement was observed for the latter 8-week period of treatment with bakumondoto. The authors do not mention whether or not there was a significant difference between the bakumondoto treatment and non-treatment groups for arms 1 and 2 combined. Neither QOL nor lung functions were affected by bakumondoto.

**8. Conclusions**

Bakumondoto may be effective for cough in elderly COPD patients.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Increases in ALP were observed in one participant in each of arms 1 and 2, however, they both completed the course of bakumondoto.

**11. Abstractor's comments**

The report by Hattori et al. (2011) was presented at a conference, so it includes questions and answers. One person asked whether cough in COPD patients was a common complaint. The presenter replied that there were many cases of exposure to toxic gas among the cases at Hiroshima University, and that some of those who complained of cough symptoms were included in the study. However, there is no mention of patients being exposed to toxic gas in the article by Mukaida et al. (2011). The authors should include such background information in their article.

**12. Abstractor and date**

Fujisawa M, 31 December 2012.