

18. Symptoms and Signs**Reference**

Irifune K, Hamada H, Ito R, et al. Antitussive effect of bakumondoto a fixed kampo medicine (six herbal components) for treatment of post-infectious prolonged cough: controlled clinical pilot study with 19 patients. *Phytomedicine* 2011; 18: 630–3. CENTRAL ID: CN-00790677, Pubmed ID: 21514123

1. Objectives

To evaluate the combined effects of bakumondoto (麦門冬湯) and a bronchodilator for prolonged cough following common cold.

2. Design

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

3. Setting

Six hospitals including Ehime University Hospital, Japan.

4. Participants

Twenty-seven adult patients who presented between February 2007 and March 2009 with prolonged cough for more than 3 weeks following a common cold. Patients whose prolonged cough was not attributable to common cold, and patients currently taking β 2 stimulants or anti-cholinergic drugs were excluded.

5. Intervention

Ultimately, 20 patients were registered after exclusions for adverse events and allocation errors.

Arm 1: TSUMURA Bakumondoto (麦門冬湯) Extract Granules 3.0 g t.i.d. before or between meals, and 50 μ g Meptin[®] (n=9).

Arm 2: Meptin[®] 50 μ g b.i.d. after breakfast and before bed (n=10).

Patients with severe cough received Medicon[®], if requested.

6. Main outcome measures

Cough intensity on a 5-point scale and timing recorded in a cough diary, VAS (visual analogue scale) score for cough intensity and frequency, and sleep quality questionnaire.

7. Main results

A significant antitussive effect (based on cough diary data: arm 1, 11 subjects; arm 2, 8 subjects) was observed in arm 1 four and five days after administration ($P<0.05$). There was no significant difference between groups for sleep quality (questionnaire) or cough improvement (VAS).

8. Conclusions

Additional treatment with bakumondoto achieves earlier antitussive results in cases of prolonged cough that do not respond to centrally acting antitussives.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Meptin[®] (50 μ g) caused palpitations or tremors in 6 participants and bakumondoto extract granules caused rash in 1.

11. Abstractor's comments

Irifune et al. cite the assertion by Fujimori et al. (1997) that bakumondoto is effective for prolonged cough after common cold, whereas standard antitussive drugs are not. They also conducted a trial to compare the antitussive effects of Medicon[®] and bakumondoto, finding that bakumondoto has more rapid effects. The present study is the first randomized controlled trial (RCT) to clarify bakumondoto's antitussive effects. The use of central antitussives containing codeine for long periods is not recommended because of their adverse effects. Thus, using bakumondoto, which has few adverse effects, is apparently advantageous. Meptin[®] (50 μ g) results in frequent adverse effects when taken in combination, so further investigation into dosage, etc. is required.

12. Abstractor and date

Fujisawa M, 31 December 2012.