18. Symptoms and Signs

Reference

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 β2 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 μg Meptin® (n=9).
Arm 2: Meptin® 50 μg 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 μg) 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 μg) 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.