

21. Others

Reference

Saruwatari J, Hisaeda S, Higa Y, et al. The *in-vivo* effect of Bakumondoto (TJ-29), a traditional Japanese medicine used for treatment of chronic airway disease, on cytochrome p450 1A2, xanthine oxidase, and N-acetyltransferase 2 activity in man. *Journal of Pharmacy and Pharmacology* 2004; 56: 1171-7. CENTRAL ID: CN-00490887, Pubmed ID: 15324486

1. Objectives

To evaluate the effect of bakumondoto (麦門冬湯) on cytochrome p450 1A2, xanthine oxidase, and N-acetyltransferase 2 activities.

2. Design

Randomized cross-over controlled trial (RCT-cross over).

3. Setting

Single facility (university), Japan.

4. Participants

Twenty-six healthy university students.

5. Intervention

Arm 1: administration of TSUMURA Bakumondoto (麦門冬湯) Extract Granules 3.0 g t.i.d. for 1 week followed by administration of the same dose of placebo at the same frequency for 1 week, with 2-week washout between both administration periods (n=13).

Arm 2: administration of placebo 3.0 g t.i.d. for 1 week followed by administration of the same dose of TSUMURA Bakumondoto (麦門冬湯) Extract Granules at the same frequency for 1 week, with 2-week washout between both administration periods (n=13).

6. Main outcome measures

Urinary cytochrome p450 1A2, xanthine oxidase, and N-acetyltransferase 2 activities (determined by a caffeine test).

7. Main results

There were no significant differences in urinary cytochrome p450 1A2, xanthine oxidase, and N-acetyltransferase 2 activities on days 1 and 7 from baseline in either arm.

8. Conclusions

Caffeine test is a safe and noninvasive screening test for herb-drug interaction measuring the ratio of urinary caffeine metabolites (cytochrome p450 1A2, xanthine oxidase, N-acetyltransferase 2). Bakumondoto did not affect cytochrome p450 1A2 (a hepatic enzyme metabolizing theophylline), xanthine oxidase, or N-acetyltransferase 2 activity, suggesting the unlikeliness of interaction.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse drug reactions occurred in the subjects receiving bakumondoto.

11. Abstractor's comments

Rather than examining data on the direct clinical effects of bakumondoto (麦門冬湯) extract granules, this study examines data on the effect of bakumondoto on urinary caffeine metabolites. The increase in Kampo medicine usage has raised interest in the interaction of Kampo with Western medicines. Hopefully this kind of research will progress further.

12. Abstractor and date

Fujisawa M, 15 June 2007, 1 April 2008, 31 December 2013.