10. Respiratory Diseases (including Influenza and Rhinitis)

Reference

Okabayashi S, Goto M, Kawamura T, et al. Non-superiority of Kakkonto, a Japanese herbal medicine, to a representative multiple cold medicine with respect to anti-aggravation effects on the common cold: a randomized controlled trial. *Internal Medicine* 2014; 53: 949-56. Ichushi Web ID: 2015097387, Pubmed ID: 24785885

1. Objectives

To evaluate the efficacy of Kakkonto (葛根湯) for alleviating early cold symptoms.

2. Design

Randomized controlled trial (RCT).

3. Setting

Nine university hospitals and 6 clinics, Japan.

4. Participants

A total of 407 cold patients aged 18 to 65 years with throat discomfort, mild chills, but no sweating who underwent a physical examination within 48 hours of onset. (The patients meeting any of the following criteria were excluded from the study: moderate or severe subjective symptoms, body temperature of 37.5°C or higher, any prior oral treatment or serious underlying disease.)

5. Intervention

Arm 1: Kracie Kakkonto (葛根湯) Extract Granules administered orally at 2.0 g t.i.d. for four days or until the symptoms disappeared (n=209).

Arm 2: Western-style multiple cold medicine (Pabron Gold-A) at 3.6 g/day for four days or until the symptoms disappeared (n=198).

6. Main outcome measures

Worsening of cold symptoms (yes or no) (i) within five days after oral administration and (ii) within seven days after oral administration.

7. Main results

In the Kakkonto arm, 41 subjects dropped out and 168 subjects were included in the analysis. In the Pabron arm, 26 subjects dropped out and 172 subjects were included in the analysis. Worsening occurred by five days in 38 subjects (22.6%) in the Kakkonto arm and 43 (25.0%) in the Pabron arm. The percentage was lower in the Kakkonto arm, but the difference between arms was not significant. Worsening occurred by seven days in 41 subjects (24.4%) in the Kakkonto arm and 52 (30.2%) in the Pabron arm. Again, the percentage was not significantly lower in the Kakkonto arm.

8. Conclusions

There is no significant difference in efficacy between Kakkonto and the multi-symptom cold medicine.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No serious adverse drug reactions were noted in the two arms. The incidence of mild adverse drug reactions including sleepiness and gastrointestinal disorder was lower in the Kakkonto arm (7 subjects [4.2%] vs 12 subjects [7.0 %]), but not significantly so.

11. Abstractor's comments

This is an important study evaluating the efficacy of Kakkonto, which is frequently used for daily treatment of cold symptoms in clinical settings, as compared with a multi-symptom cold medicine. Although the anti-aggravation effects of Kakkonto on cold symptoms were evaluated in the present study with sample size based on the previous study, a significant efficacy was not demonstrated. One of the limitations of the study, according to the authors, was the difficulty with demonstrating evidence based on subjective evaluation. In this study, the efficacy was evaluated in terms of cold symptom prevention, but not symptom improvement in actual clinical settings. The inclusion of patients with mild symptoms may have affected the study's ability to detect a significant difference. Although the study design seemed to be appropriate for determining Kakkonto's efficacy as a self-medication and its safety, more studies are anticipated after re-examining the existing severity classification rules or outcome measures to be evaluated.

12. Abstractor and date

Koike H, 31 March 2017.