21. Others

Reference

1. Objectives
To isolate the indicator ingredients of Kampo medicines and evaluate their equivalence with extract and decoction.

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

3. Setting
Public recruitment of healthy volunteers from a clinical study registry of a university hospital medical information network center, Japan.

4. Participants
Six healthy volunteers.

5. Intervention
Since the method of allocation to treatment arms was not described in the article, the treatment arms are described in terms of treatment regimen.

Arm 1: Administration orally of kakkonto (葛根湯) decoction (of Pueraria Root 8 g, Ephedra Herb 4 g, Jujube 4 g, Cinnamon Bark 3 g, Peony Root 3 g, Glycyrrhiza 2 g, and ginger 1 g heated and extracted in 500 mL of water, filtered through 4 layers of gauze, and adjusted to 250 mL), washout for 2 weeks, and finally administration of Kracie Kakkonto (葛根湯) Extract Fine Granules 7.5 g (n=6).

Arm 2: Administration orally of Kracie Kakkonto (葛根湯) Extract Fine Granules 7.5 g, washout for 2 weeks, and administration of its decoction (n=6).

6. Main outcome measures
Blood concentrations of ephedrine and pseudoephedrine at 15, 13, 60, 120, and 240 minutes after treatment.

7. Main results
No inter-arm difference in post-dose blood concentrations of ephedrine and pseudoephedrine and absorption parameters (Tmax, Cmax, AUC, and MRT) was found.

8. Conclusions
The equivalence with kakkonto extract and decoction can be established from blood levels of ephedrine and pseudoephedrine, which are indicator ingredients according to the Japanese Pharmacopeia.

9. From Kampo medicine perspective
None.

10. Safety assessment in the article
Not mentioned.

11. Abstractor’s comments
This study was conducted to evaluate the equivalence of Kampo extract with decoction, the predominant form of this Kampo treatment in daily use. When ephedrine and pseudoephedrine, the main ingredients in kakkonto, were selected as indicator ingredients, their post-dose blood concentrations and absorption rates were similar between the extract and decoction formulation. These results suggested that the various drug formulations prescribed in clinical settings were equally effective and that these indicator ingredients selected from the Japanese Pharmacopeia may be used to show the equivalence between formulations. This study is a pilot study of just six subjects assigned to two groups. Considering the differences in treatment response between individuals, an increased number of study subjects will be required to obtain more generalizable results. ePilot studies, such as this study, which evaluate pharmacokinetics of Kampo crude ingredient absorption, are of major importance to clinicians who need to anticipate the possible effects of Kampo medicines in daily practice. Further studies are anticipated.

12. Abstractor and date
Ushiroyama T, 31 March 2017