21. Others

Reference

Shimakura K, Mineshita S, Sanaka M, et al. Effects of kakkonto on the pharmacokinetics of phenacetin in human serum and saliva*. *Rinsho Yakuri* (*Japanese Journal of Clinical Pharmacology and Therapeutics*) 1994; 25: 229–30 (in Japanese).

1. Objectives

To evaluate the effects of kakkonto (葛根湯) on the pharmacokinetics of phenacetin.

2. Design

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

3. Setting

One university hospital, Japan.

4. Participants

Eleven healthy subjects.

5. Intervention

Arm 1: phenacetin 12 mg/kg (n=6).
Arm 2: phenacetin 12 mg/kg + TSUMURA Kakkonto (葛根湯) Extract Granules 2 sachets (containing 1250 mg of kakkonto dry extract / sachet) (n=5).
Crossed over with a 7-day or longer washout period between arms.

6. Main outcome measures

Blood and saliva concentrations of phenacetin and its metabolites, acetaminophen and glucuronide.

7. Main results

There were no between-arm significant differences in C_{max} (post-dose maximum blood concentration) and AUC (area under the blood concentration-time curve: a measure of efficacy reflecting the percent drug absorption or bioavailability) of acetaminophen in either blood or saliva. The time-course of acetaminophen concentration showed a tendency toward higher concentration in saliva in arm 2 than in arm 1, but no between-arm difference in concentration in blood.

8. Conclusions

Kakkonto seems to only slightly affect the pharmacokinetics of phenacetin, acetaminophen, or glucuronide.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This study would have been probably designed to demonstrate kakkonnto combined with phenacetin increases the concentration of acetaminophen, a metabolite of phenacetin. Since the authors states that "at present, combination Kampo medicines containing western cold remedies and Kampo medicines such as kakkonto extract are commercially available, and some studies report the usefulness of Kampo medicines for drug efficacy of western medicines." In this study, concentration in saliva was measured because it was the focus of therapeutic drug monitoring at that time.

12. Abstractor and date

Fujisawa M, 15 October 2008, 1 June 2010, 31 December 2013.