21. Others

Reference

Qi J, Toyoshima A, Honda Y, et al. Pharmacokinetic study on acetaminophen: interaction with a Chinese medicine. *Journal of Medical and Dental Sciences* 1997; 44: 31-5. CENTRAL ID: CN-00145359, Pubmed ID: 9385040

1. Objectives

To evaluate the effect of kakkonto (葛根湯) on the pharmacokinetics of acetaminophen.

2. Design

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

3. Setting

No study site was specified (authors affiliated with the Department of Preventive Medicine, Division of Social Medicine, Medical Research Institute, Tokyo Medical and Dental University), Japan.

4. Participants

Nineteen healthy volunteers.

5. Intervention

Arm 1: single oral dose of PL glanules containing 150 mg of acetaminophen) in combination with TSUMURA Kakkonto (葛根湯) Extract Granules (containing 1250 mg of extract) (n=19).

Arm 2: single oral dose of PL (containing 150 mg of acetaminophen) (n=19).

There was a 1-week washout period.

6. Main outcome measures

Blood concentrations of acetaminophen (APAP) and APAP glucuronide (measured by high performance liquid chromatography [HPLC] before and 0.5, 1, 2, 3, and 4 hours after administration of APAP) were used to calculate the maximum blood concentration (C_{max}), time to C_{max} (t_{max}), half-life in blood ($t_{1/2}$), and area under the blood concentration curve (AUC).

7. Main results

There were no between-arm differences in C_{max}, t_{max}, $t_{1/2}$, or AUC of APAP or APAP glucuronide.

8. Conclusions

The pharmacokinetics of acetaminophen is not affected by concomitant administration of kakkonto.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse drug reactions were reported.

11. Abstractor's comments

This study measured blood acetaminophen concentration after coadministration of kakkonto with acetaminophen (which are commonly co-administered in clinical practice). Adverse reactions to acetaminophen were not affected by administration of kakkonto in combination with PL. In another study involving volunteers, however, it was reported that the blood APAP concentration was higher after co-administration of kakkonto (5 g; use of granules or extract bulk powder, not specified) in combination with APAP (12 mg/kg). In rats that received APAP (10 mg/kg) plus kakkonto (100 or 200 mg/day) for 1 week, the APAP level was significantly higher in the kakkonto (200 mg/day) group than in the distilled water group only at 0.25 hour after APAP administration. Therefore, since drug interaction may affect the blood acetaminophen concentration depending on the dose and/or treatment duration of kakkonto and acetaminophen, a randomized clinical study might have been more useful if co-administration was frequent. Nevertheless, the study was very valuable because it showed that the blood acetaminophen concentration was not affected by a single co-administration at commonly used doses.

12. Abstractor and date

Goto H, 19 September 2008, 1 June 2010, 31 December 2013.