

21. Others

References

Ohnishi N, Yonekawa Y, Fumihara T, et al. **Studies on interactions between traditional herbal and Western medicines, II. Lack of pharmacokinetic interaction between shoseiryu-to and carbamazepine in healthy volunteers.** *TDM Kenkyu (Japanese Journal of Therapeutic Drug Monitoring)* 1999; 16: 399-404. Ichushi Web ID: 2000070928 [MOL](#), [MOL-Lib](#)

Yonekawa Y, Ohnishi N, Kitano N, et al. Drug interaction with Kampo medicines (2): kinetic characteristics of carbamazepine combined with shoseiryuto in healthy volunteers. *TDM Kenkyu (Japanese Journal of Therapeutic Drug Monitoring)* 1999; 16: 191-2. [MOL](#), [MOL-Lib](#)

1. Objectives

To evaluate the effect of shoseiryuto (小青竜湯) on blood carbamazepine concentration.

2. Design

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

3. Setting

None (authors belong to the Department of Hospital Pharmacy, Kyoto Pharmaceutical University), Japan.

4. Participants

Four healthy adult males.

5. Intervention

Since allocation of patients to these treatment arms is not mentioned, the treatment arms are described in terms of treatment regimen.

Arm 1: administration of 9.0 g/day of TSUMURA Shoseiryuto (小青竜湯) Extract Granules in 3 divided doses before meals for 7 days and 200 mg of carbamazepine in the morning of day 4 (n=4).

Arm 2: administration of 200 mg of carbamazepine (n=4).

A two-week period intervened between the changeover from the arm 1 intervention to the arm 2 intervention.

6. Main outcome measures

Concentrations of carbamazepine and its metabolite carbamazepine-10,11-epoxide in blood sampled before, and 1.5, 4, 8, 24, 48, and 72 hr after administration of carbamazepine.

7. Main results

Combination with shoseiryuto did not affect the following parameters of carbamazepine and its metabolite carbamazepine-10,11-epoxide in blood: the maximum blood concentration; time to reach the maximum blood concentration; slope of the elimination phase; elimination half-life; area under the plasma concentration-time curve; and mean residence time.

8. Conclusions

Oral administration of shoseiryuto does not affect blood carbamazepine concentration.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This study objectively demonstrated that combination of shoseiryuto does not affect blood carbamazepine concentration, which is susceptible to the effects of various drugs. This study does not evaluate the efficacy of the Kampo medicine, but is considered meaningful, given that Western and Kampo medicines are commonly combined in clinical practice.

12. Abstractor and date

Goto H, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.