21. Others

Reference

Hasegawa T, Yamaki K, Nadai M, et al. Lack of effect of Chinese medicines on bioavailability of ofloxacin in healthy volunteers. *International Journal of Clinical Pharmacology and Therapeutics* 1994; 31: 57-61. CENTRAL ID: CN-00102144, Pubmed ID: 8004359

1. Objectives

To evaluate the effect of Kampo medicines on bioavailability of ofloxacin (OFLX) in healthy volunteers.

2. Design

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

3. Setting

Single institution (Nagoya University School of Medicine), Japan.

4. Participants

Seven healthy male volunteers (age 23–30 years).

5. Intervention

Arm 1: treatment with OFLX 200 mg.
Arm 2: treatment with OFLX 200 mg + TSUMURA Shosaikoto (小柴胡湯) Extract Granules 2.5 g.
Arm 3: treatment with OFLX 200 mg + TSUMURA Rikkunshito (六君子湯) Extract Granules 2.5 g.
Arm 4: treatment with OFLX 200 mg + TSUMURA Saireito (柴苓湯) Extract Granules 3.0 g.
Test drugs were administered orally with 150 mL of water at 8:30 a.m. at one-week intervals.

6. Main outcome measures

Blood concentration of OFLX and the percentage of OFLX excreted in 24-hour urine at 0.5, 1, 1.5, 2, 3, 4, 6, 8, and 12 hours after the administration; pharmacokinetic analysis.

7. Main results

There were no significant between-arm differences in bioavailability. The percentage of OFLX excreted in 24-hour urine in arm 1 (mean±SEM, 80.6±3.9%) was not significantly different from that after OFLX co-administration with shosaikoto (arm 2; 79.7±5.1%), rikkunshito (arm 3; 76.8±2.3%), or saireito (arm 4; 80.3±5.3%).

8. Conclusions

Kampo medicines have no significant effect on bioavailability of ofloxacin in healthy volunteers.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

It was speculated that those Kampo medicines studied don't have much effect on metabolism of quinolones and therefore can be safely co-administered with those agents. However, since this was an evaluation in healthy volunteers, it should be kept in mind that Kampo medicines might affect bioavailability in certain circumstances, such as in the disease state.

12. Abstractor and date

Namiki T, 29 December 2008, 6 January 2010, 1 June 2010, 31 December 2013.