Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

21. Others Reference

Hasegawa T, Yamaki K, Muraoka I, et al. Effects of traditional Chinese medicines on pharmacokinetics of levofloxacin. *Antimicrobial Agents and Chemotherapy* 1995; 39: 2135-37. CENTRAL ID: CN-00119767, Pubmed ID: 8540731

1. Objectives

To determine the pharmacokinetics of levofloxacin (Cravit[®]) when coadministered with hochuekkito (補中益気湯), rikkunshito (六君子湯), or juzentaihoto (十全大補湯), and to gain insights into the interactions between them.

2. Design

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

3. Setting

Second Department of Internal Medicine, Nagoya University School of Medicine, Japan.

4. Participants

Eight male volunteers with no abnormal findings on medical history, routine blood biochemistry, and urinalysis.

5. Intervention

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

Arm 1: treatment with levofloxacin 200 mg alone.

Arm 2: treatment with levofloxacin 200 mg + TSUMURA Hochuekkito (補中益気湯) Extract Granules 2.5 g.

Arm 3: treatment with levofloxacin 200 mg + TSUMURA Rikkunshito (六君子湯) Extract Granules 2.5 g. Arm 4: treatment with levofloxacin 200 mg + TSUMURA Juzentaihoto (十全大補湯) Extract Granules 2.5 g.

All the 8 patients underwent arm 1 through arm 4 treatments, with a wash-out period of 7 days between treatments.

6. Main outcome measures

Concentrations of levofloxacin in blood and urine (determined by high-performance liquid chromatography).

7. Main results

All three Kampo formulations studied had no effect on metabolism of levofloxacin.

8. Conclusions

Kampo medicines have no effect on the pharmacokinetics of levofloxacin. Further investigations, including investigations of other Kampo formulations, are needed.

9. From Kampo medicine perspective None.

10. Safety assessment in the article No adverse events occurred.

11. Abstractor's comments

This paper describes the effect of Kampo medicines on the pharmacokinetics of a typical antibiotic. It has been reported that Kampo medicines have considerable effects on the intestinal environment. The demonstration of no effect on the pharmacokinetics of at least one antibiotic in this study is of great significance, considering that western prescription medications and Kampo medicines are commonly coadministered in current clinical practice.

12. Abstractor and date

Nakata H, 10 January 2009, 31 December 2013.