

Evidence Reports of Kampo Treatment

Task Force for Evidence Reports, the Japan Society for Oriental Medicine

Note) The quality of this RCT has not been validated by the EBM committee of the Japan Society for Oriental Medicine.

21. Others

Reference

Horii C, Okonogi A, Studies on bioequivalence of shoseiryuto decoction and its extract preparation (I), *Shoyakugaku zasshi (Journal of Natural Medicines)* 2014; 68: 65-9. Ichushi Web ID: 2014391859 [MOL](#), [MOL-Lib](#)

1. Objectives

To evaluate the bioequivalence of shoseiryuto (小青竜湯) extract and its decoction.

2. Design

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

3. Setting

A university hospital medical center, Japan.

4. Participants

Six volunteers recruited publicly.

5. Intervention

Since the method of treatment assignment was not apparent from the article, treatment arms are defined by drug formulation.

Arm 1: Kracie Shoseiryuto (小青竜湯) Extract Fine Granules at 6.0 g for 2 weeks.

Arm 2: Shoseiryuto (小青竜湯) decoction (Ephedra Herb 3 g, Peony Root 3 g, Processed Ginger 3 g, Glycyrrhiza 3 g, Cinnamon Bark 3 g, Asiasarum Root 3 g, Schisandra Fruit 3 g, and Pinellia Tuber 6 g)

6. Main outcome measures

Blood concentrations of ephedrine and pseudoephedrine (indicator constituents of Ephedra Herb).

7. Main results

There was no significant difference in blood concentrations of ephedrine and pseudoephedrine between Arm 1 and Arm 2 at each timepoint.

8. Conclusions

Concentrations of the indicator constituents in Ephedra Herb seem to be equivalent between the shoseiryuto decoction and shoseiryuto extract.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No special problems were noted.

11. Abstractor's comments

This article showed no significant difference in blood levels of ephedrine and pseudoephedrine between the decoction and extract. As mentioned in the Discussion in this article, however, additional comparisons including comparison of paeoniflorin of Peony Root and glycyrrhizic acid of Glycyrrhiza and an examination of the influence of absorption and metabolism would make this article's results more meaningful. However, even though the decoction and extract produced the same blood levels of the indicator constituents of Ephedra Herb, the efficacy of the extract was not fully demonstrated.

12. Abstractor and date

Nakata H, 31 March 2017.