

21. Others**Reference**

Munekage M, Ichikawa K, Kitagawa H, et al. Population pharmacokinetic analysis of daikenchuto, a traditional Japanese medicine (Kampo) in Japanese and US health volunteers. *Drug Metabolism and Disposition* 2013; 41: 1256-63. CENTRAL ID: CN-0964576, Pubmed ID: 23545807

1. Objectives

To analyze the blood kinetics of indicator ingredients in daikenchuto (大建中湯).

2. Design

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

3. Setting

Kochi Medical School Hospital, Japan, and a center in USA.

4. Participants

Healthy volunteers: 19 Japanese and 36 American.

5. Intervention

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

Arm 1: TSUMURA Daikenchuto (大建中湯) Extract Granules 2.5 g (18 Japanese and 33 Americans).

Arm 2: TSUMURA Daikenchuto (大建中湯) Extract Granules 5 g (19 Japanese and 34 Americans).

Arm 3: TSUMURA Daikenchuto (大建中湯) Extract Granules 10 g (19 Japanese and 33 Americans).

6. Main outcome measures

Hydroxyl- α -sanshool, hydroxyl- β -sanshool, 6-shogaol, 10-shogaol, and ginsenoside Rb1 blood kinetics.

7. Main results

The indicator ingredients, hydroxyl- α -sanshool, hydroxyl- β -sanshool, 6-shogaol, and 10-shogaol demonstrated blood kinetics in line with the one- or two-compartment model with bolus input; however, only ginsenoside Rb1 demonstrated blood kinetics in line with the one-compartment model with nonlinear extravascular input. Blood plasma hydroxyl- α -sanshool and hydroxyl- β -sanshool concentrations differed significantly between the Japanese and the Americans.

8. Conclusions

Of the indicator ingredients in daikenchuto, Japanese Pepper-/Processed Ginger-derived ingredients and Ginseng Radix-derived ingredients differed in blood kinetics. While concentrations of blood plasma hydroxyl- α -sanshool and hydroxyl- β -sanshool differed between Japanese and Americans, differences in BMI, age and race may also have an effect.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

The blood kinetics of five indicator ingredients in daikenchuto extract were measured in this study. The blood kinetics of low molecular weight compounds such as hydroxyl- α -sanshool, hydroxyl- β -sanshool, 6-shogaol, and 10-shogaol, and that of high molecular weight compounds such as ginsenoside Rb1 differ vastly, pointing to the complexity of the blood kinetics of multicomponent Kampo preparations. Given that differences were observed between the blood concentrations of the ingredient sansho in the Japanese and the Americans, it may be important to adjust dosages according to circumstances, considering that the kinetics differ among ingredients, while taking race and physique into consideration. The Japanese study referred to in this report appears to be the identical study reported by Munekage M, Kitagawa H, Ichikawa K, et al. in *Drug Metabolism and Disposition* 2011; 39: 1874-8: Pharmacokinetics of daikenchuto, a traditional Japanese medicine (Kampo) after single oral administration to healthy Japanese volunteers.

12. Abstractor and date

Nakata H, 6 June 2015.