

21. Others

Reference

Munekage M, Kitagawa H, Ichikawa K, et al. Pharmacokinetics of daikenchuto, a traditional Japanese medicine (Kampo) after single oral administration to healthy Japanese volunteers. *Drug Metabolism and Disposition* 2011; 39: 1784-8. Pubmed ID: 21724872

1. Objectives

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

2. Design

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

3. Setting

Surgery Department, Kochi Medical School Hospital, Japan.

4. Participants

Nineteen healthy volunteers (including three volunteers who did not meet the criteria and were excluded).

5. Intervention

Groupings by administration pattern were not indicated, so the arms are described in terms of drug groups.

Arm 1: TSUMURA Daikenchuto (大建中湯) Extract Granules 2.5 g group (n=15).

Arm 2: TSUMURA Daikenchuto (大建中湯) Extract Granules 5 g group (n=16).

Arm 3: TSUMURA Daikenchuto (大建中湯) Extract Granules 10 g group (n=16).

6. Main outcome measures

Hydroxyl- α -sanshool, hydroxyl- β -sanshool, 6-shogaol, 10-shogaol, ginsenoside Rb1, and ginsenoside Rg1 blood kinetics (AUC, C_{max} , $t_{1/2}$, t_{max}).

7. Main results

Hydroxyl- α -sanshool, hydroxyl- β -sanshool, 6-shogaol, and 10-shogaol reached t_{max} in 0.2–0.5 hours and were rapidly eliminated from the blood; however, ginsenoside Rb1 and ginsenoside Rg1 reached t_{max} in 1–4 hours and were more slowly eliminated from the blood. Increases in blood concentrations of hydroxyl- α -sanshool, hydroxyl- β -sanshool, 6-shogaol, and 10-shogaol were dosage dependent, but increases in blood concentrations of ginsenoside Rb1 and ginsenoside Rg1 were dosage independent.

8. Conclusions

Of the six indicator components in daikenchuto, increases in the blood concentrations of the sansho- and kankyo-derived components are dose dependent but increases in those of ginseng-derived components are dose independent.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Six adverse events (abnormal laboratory values) occurred in four participants, but a causal relationship with daikenchuto was excluded.

11. Abstractor's comments

The blood kinetics of six indicator components in daikenchuto extract were analyzed in this study. There are distinct differences between the blood kinetics of low molecular weight compounds such as hydroxyl- α -sanshool, hydroxyl- β -sanshool, 6-shogaol, and 10-shogaol, and high molecular weight compounds such as ginsenoside Rb1 and ginsenoside Rg1, which points to the complexity of the blood kinetics of Kampo preparations with their wide arrays of components. This paper suggests the possibility that prescriptions considered to be deficiency-pattern treating formulae or *hozai* (補劑) (because they contain a wide array of high molecular weight compounds) do not act in a dosage dependent manner.

12. Abstractor and date

Nakata H, 31 December 2013.