

**11 Gastrointestinal, Hepato-Biliary-Pancreatic Diseases****Reference**

Manabe N, Camilleri M, Rao A, et al. Effect of Daikenchuto (TU-100) on gastrointestinal and colonic transit in humans. *American Journal of Physiology. Gastrointestinal and Liver Physiology* 2010; 298: G970–5.

**1. Objectives**

To evaluate the effects of daikenchuto (大建中湯) on gastrointestinal and colonic transit and bowel function in healthy humans.

**2. Design**

Double-blind randomized controlled trial (DB-RCT).

**3. Setting**

Mayo Clinic, US.

**4. Participants**

Sixty healthy adults (18–65 years old) without gastrointestinal disorders recruited by advertisement. Those with a history of allergic reactions to egg, ginseng, ginger, and Sichuan pepper were excluded.

**5. Intervention**

Treatment was administered t.i.d. immediately before meals for 5 consecutive days. Participants and study personnel were blinded (double-blind) to treatment assignment.

Arm 1: daikenchuto (大建中湯) (manufacturer, not specified) 2.5 g t.i.d. (n=19).

Arm 2: daikenchuto (大建中湯) (manufacturer, not specified) 5 g t.i.d. (n=20).

Arm 3: identical placebo (n=21).

**6. Main outcome measures**

Primary outcomes: gastric emptying half-time (GE  $t_{1/2}$ ) measured by scintigraphy; colonic geometric center at 24 h (GC24); ascending colon emptying half-time (AC emptying  $t_{1/2}$ ).

Secondary outcomes: colonic geometric center at 4 h and 48 h (GC4, GC48); colonic filling at 6 h; stool frequency and consistency (self-assessed using the Bristol Stool Form Scale).

**7. Main results**

There was a difference in colonic filling at 6 h between both daikenchuto groups and the placebo group ( $P=0.04$ ). Pair-wise comparisons between Arm 1 and Arm 3 and between Arm 2 and Arm 3 showed no significant differences. Daikenchuto 7.5 g/day tended to accelerate ascending colon emptying half-time ( $P=0.07$ ) and daikenchuto at both doses tended to raise GC24 ( $P=0.63$ ). However, daikenchuto had no meaningful effects on gastric emptying half-time ( $P=0.45$ ), stool frequency ( $P=0.80$ ), or stool consistency ( $P=0.33$ ).

**8. Conclusions**

Daikenchuto accelerated colonic filling at 6 h and ascending colon emptying half-time in healthy humans, suggesting that it promotes small bowel motility and hastens ascending colon transit.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

One subject receiving daikenchuto 7.5 g/day had increased creatine phosphokinase (CPK) 1 month after receiving the study medication, which was discovered when the subject presented to the emergency department for muscle pain. With no evidence of myopathy, CPK level returned to normal at 4 months without intervention.

**11. Abstractor's comments**

This is a well-designed DB-RCT. Regrettably, no statistically significant difference was detected, which may be partly because the study population was healthy volunteers, considering the characteristics of Kampo medicine. The results of future RCTs being planned by the authors in patients with gastrointestinal disorders, including irritable bowel syndrome and constipation, are expected.

**12. Abstractor and date**

Tsuruoka K, 7 January 2011.