

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases**References**

Numata T, Takayama S, Tobita M, et al. Traditional Japanese medicine daikenchuto improves functional constipation in poststroke patients. *Evidence-Based Complementary and Alternative Medicine* 2014: 1-8. doi: 10.1155/2014/231258

Numata T, Takayama S, Iwasaki K, et al. A prospective comparative trial using the Kampo medicine, daikenchuto (大建中湯) for constipation in poststroke patients. *Kampo & the Newest Therapy* 2015; 24:145-152

1. Objectives

To evaluate the efficacy and safety of daikenchuto (大建中湯) as treatment for functional constipation in poststroke patients.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

Six hospitals.

4. Participants

Thirty-four patients (17 females / 17 males) who were diagnosed with functional constipation according to Roma III diagnostic criteria from September 2012 to December 2013 and who remained stable over 6 months or longer after having suffered cerebral hemorrhage, cerebral infarct, or subarachnoid hemorrhage.

5. Intervention

Arm 1: Common treatment for relief of constipation including laxative, enema, fecal disimpaction, etc. as well as oral administration of TSUMURA Daikenchuto (大建中湯) Extract Granules 5g divided in three doses per day before each meal or tube administration for 4 weeks (n=17).

Arm 2: Common treatment for relief of constipation including laxative, enema, fecal disimpaction, etc. for 4 weeks (n=17).

6. Main outcome measures

Constipation scoring system (CSS), gas volume score (GVS), calcitonin-gene related peptide (CGRP) concentration in blood.

7. Main results

Patients in arm 1 showed a statistically significant decrease in CSS ($P < 0.01$), and also in GVS ($P = 0.03$) compared to arm 2. The CGRP concentration in blood was similar between arm 1 and arm 2.

8. Conclusion

Daikenchuto is effective in improvement of constipation and retention of gas in the abdominal cavity in poststroke patients.

9. From Kampo medicine perspective

Daikenchuto is effective for constipation in yin pattern (陰証, insho) patients with loss of appetite and decreased gastrointestinal tract function.

10. Safety assessment in the article

Adverse reaction was not observed in the daikenchuto-administered arm.

11. Abstractor's comments

This paper reports the results of a clinical trial investigating the efficacy of daikenchuto for the treatment of constipation in poststroke patients. This RCT is significant for its demonstration of daikenchuto's efficacy in poststroke patients who often suffer from constipation and distension. Moreover, while hypothetically the effect of daikenchuto on constipation is mediated via CGRP, this RCT found no significant difference in blood levels of CGRP in spite of daikenchuto's clinical efficacy. This conflicting finding has warrants further basic studies of daikenchuto. As mentioned in this paper, some studies report that daikenchuto is not effective for constipation in other circumstances; therefore, further studies are anticipated to determine the efficacy of daikenchuto in a broader spectrum of constipation.

12. Abstractor and date

Koike H, 31 March 2017.