

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

Reference

Acosta A, Camilleri M, Linker-Nord S, et al. A pilot study of the effect of daikenchuto on rectal sensation in patients with irritable bowel syndrome. *Journal of Neurogastroenterological Motility* 2016; 22: 69-77. Pubmed ID: 26486374

1. Objectives

To evaluate the effects of daikenchuto (大建中湯) on rectal sensation in patients with irritable bowel syndrome (IBS).

2. Design

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

3. Setting

One hospital.

4. Participants

Forty female IBS patients who fulfilled the Rome III criteria.

5. Intervention

Arm 1: TSUMURA Daikenchuto (大建中湯) Extract Granules (15g t.i.d for 14 days) (n=20)

Arm 2: Placebo granules (15g t.i.d for 14 days) (n=20)

6. Main outcome measures

Primary outcome measures: ① Feeling of urgency in reaction to 32mmHg intrarectal expansion pressure (quantified on 100mm VAS); ② pain threshold in reaction to bowel expansion

Secondary outcome measures: ① Physiological measures (rectal sensation threshold, etc.); ② clinical measures (bowel movement frequency, etc.) ③ QOL score

7. Main results

No significant differences were observed between the 2 groups in any of the primary or secondary outcome measures.

8. Conclusions

Daikenchuto does not display any significant effect on rectal sensation in patients with IBS.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

The authors mention in the abstract that they evaluated safety, but there is no mention in the results.

11. Abstractor's comments

This report is valuable for having evaluated the effects of daikenchuto in IBS patients using a method of measuring rectal sensation with an intrarectal balloon. The authors raised various reasons for the daikenchuto not demonstrating a significant effect: while the Kampo preparation they used was TSUMURA Daikenchuto (大建中湯) Extract Granules (TU-100), the participants were Americans, who have a different pharmacokinetics to Japanese people; the number of cases was small; the administration period was short; and the daikenchuto dosage was single-dose. It is certainly possible that these factors affected the results of this study. It is unclear whether there would be any significance in repeating a similar DB-RCT, but increasing the number of cases, extending the administration period, and changing the daikenchuto dosage.

12. Abstractor and date

Motoo Y, 18 May 2020.