11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

Reference

Suzuki Y, Itoh H, Yamamura R, et al. Significant increase in salivary substance P level after a single oral dose of Japanese herbal medicine Dai-kenchu-to in humans. *Biomedicine & Aging Pathology* 2012; 2: 81-4. Pubmed ID: 23589717

1. Objectives

To evaluate the effects of daikenchuto (大建中湯) on salivary secretion and salivary neuropeptide levels in humans after a single oral dose.

2. Design

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

3. Setting

Department of Pharmacy, Oita University Hospital, Japan.

4. Participants

Five nonsmoking healthy male volunteers aged 25 to 31 years.

5. Intervention

Since allocation of patients to treatment arms is not mentioned, the treatment arms are described in terms of treatment regimen.
Arm 1: Single dose of TSUMURA Daikenchuto (大建中湯) Extract Granules 15 g with 200 mL of water
Arm 2: Single dose of placebo (lactose; dosage not specified) with 200 mL of water
Subjects were crossed over to the alternate arm after a 1-month interval.

6. Main outcome measures

The volume of saliva collected from subjects at rest in a relaxed state at 20, 40, 60, 90, 120, 180, and 240 minutes after administration, and salivary levels of substance P-like immunoreactive substances (SP-IS), calcitonin gene-related peptide (CGRP)-IS, and vasoactive intestinal polypeptide (VIP)-IS measured by enzyme immunoassays.

7. Main results

Although differences in salivary volume between arms 1 and 2 were not significant, the volume increased 1.2–1.5 times during the 20–120 minutes after administration. The salivary SP-IS level in arm 1 was significantly increased at 20, 40, and 60 minutes after administration, compared to that in arm 2 ($P<0.05$). The salivary volume was significantly positively correlated with the SP-IS level ($r=0.42$, $P=0.0062$). There were no significant differences in CGRP-IS and VIP-IS levels between arms 1 and 2.

8. Conclusions

Daikenchuto increases salivary secretion by increasing the level of substance P. Patients with xerostomia will benefit from treatment with daikenchuto.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

The relevant references show that the group to which the authors belong has studied the effect of daikenchuto on neuropeptides in human plasma, effect of pilocarpine on neuropeptides in human saliva, and effect of hangekobokuto (半夏厚朴湯) on neuropeptides in human plasma and saliva since around year 2000. Therefore, this RCT is considered clinical verification of evidence from a series of their studies with an RCT design. Since the present study was conducted in healthy subjects, it is premature to conclude that daikenchuto is effective for xerostomia. This study, however, is a starting point for the verification of new beneficial effects of daikenchuto and hopefully will lead to further development of their research.

12. Abstractor and date

Fujisawa M, 6 June 2015.