18. Symptoms and Signs

Reference

Sasaki S, Oumi A, Kumeda M, et al. Evaluation of nutrition improvement effects of hochuekkito (補中益気湯) in patients with tube feeding. *Science of Kampo Medicine 2014 (in Japanese)*, 38: 263-6. Ichushi Web ID: 2015111016

1. Objectives

To evaluate the nutrition improvement effects of hochuekkito (補中益気湯) in patients with tube feeding.

2. Design

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

3. Setting

One hospital.

4. Participants

Twenty-four patients with tube feeding.

5. Intervention

Arm 1: Administration of TSUMURA Hochuekkito (補中益気湯) Extract Granules 2.5g t.i.d. for 3 months (n=12).
Arm 2: Lactose 2.5g colored with decaffeinated coffee t.i.d. for 3 months (n=12).

6. Main outcome measures

Serum albumin value, prognostic nutritional index, area of the brachial muscle, controlling nutritional status (CONUT) score, rate of fever of 37°C or higher 3 months before and after the administration.

7. Main results

As 1 and 3 patients dropped out in arm 1 and in arm 2, respectively, 11 patients in arm 1 and 9 patients in arm 2 were studied. Serum albumin level was significantly higher in arm 1 than arm 2 at month 3 (P=0.032). There were no significant between-arm differences in prognostic nutritional index, area of the brachial muscle, CONUT score after administration, and rate of fever of 37°C or higher for 3 months before and after the administration.

8. Conclusions

Hochuekkito increases serum albumin levels in patients with tube feeding.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

In the hochuekkito-administered group, 1 patient died, and in placebo-administered group, 2 patients died.

11. Abstractor's comments

This paper reports nutrition improvement after hochuekkito administration in patients with tube feeding. A number of retrospective studies have suggested the efficacy of hochuekkito and other Kampo medicines to improve nutrition rationally; however, this study was significant because it was an actual double-blind prospective study showing the efficacy of hochuekkito. In the study, the endpoints had not been defined either primary or secondary endpoints and designed to detect any endpoints with statistical significance among the 5 endpoints. Therefore, we have to admit that improvement in serum albumin level (the only endpoint with statistical significance) may be accidental. In addition, the number of patients in the study was insufficient and the investigators appeared to proceed through the trial in a disorganized undisciplined manner without knowing the appropriate duration of evaluation. Thus the trial is only important as an exploratory study, and a new trial with defined primary endpoints, appropriate number of patients, and appropriate evaluation period is anticipated as a next step.

12. Abstractor and date

Koike H, 31 March 2017.