

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

Ito J, Ito Y, Asai M, et al. Efficacy of Saireito (TSUMURA) for post-infectious dyspepsia in infants: comparison with intestinal regulators*. *Shonika Shinryo (Journal of Pediatric Practice)* 1992; 55: 2089-92 (in Japanese). Ichushi Web ID: 1993113987

1. Objectives

To evaluate the efficacy of Saireito (柴苓湯; TSUMURA) compared with that of intestinal regulators for treatment of post-infectious dyspepsia in infants.

2. Design

Randomized controlled trial (RCT).

3. Setting

Single institution (Yokkaichi Municipal Hospital), Japan.

4. Participants

Eighty-seven infants (age range, 4 months to 5 years 10 months old; range of body weight, 7 to 19 kg) who visited the outpatient department with presenting symptoms of cough, fever, or diarrhea (after exclusion of thirty-nine infants who were hospitalized during the study period).

5. Intervention

Arm 1: treatment with TSUMURA Saireito (柴苓湯) Extract Granules 1.5 g b.i.d. (n=32).

Arm 2: treatment with TSUMURA Saireito (柴苓湯) Extract Granules 1.5 g b.i.d. + albumin tannate 0.1 g/kg/day + natural aluminum silicate 0.1 g/kg/day + resistant lactobacillus preparation 0.1 g/kg/day (n=21).

Arm 3: treatment with albumin tannate 0.1 g/kg/day + natural aluminum silicate 0.1 g/kg/day + resistant lactobacillus preparation 0.1 g/kg/day (n=22).

Arm 4: no treatment with antidiarrheal drugs or intestinal regulators (n=12).

6. Main outcome measures

Symptoms (including the number of episodes and type of diarrhea) and food intake for 7 days were scored (using the 7-day questionnaire, which was distributed to and completed by the patient's mother).

7. Main results

There were no among-arm differences in age, body weight, and symptoms. Diarrhea scores were significantly higher in arm 2 than in arm 3 at 1 day; in arms 1 and 2 than in arm 3 at 2 days; and in arm 1 than in arm 3 at 3 days. The number of patients who withdrew from the study was 1 from arm 1, 0 from arm 2, 15 from arm 3, and 23 from arm 4.

8. Conclusions

Saireito was likely to be useful for treating post-infectious dyspepsia in infants.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This paper describes a determination of the efficacy of saireito for post-infectious dyspepsia in infants. Although it was a small study, the report is valuable considering the scarcity of evidence in the field of pediatric gastrointestinal diseases. Lower percentage of saireito-treated patients required hospitalization. Thus, saireito may not only improve symptoms, but also prevent aggravation of symptoms.

12. Abstractor and date

Oikawa T, 19 September 2008, 6 January 2010, 1 June 2010.