

**1. Infections (including Viral Hepatitis)****Reference**

Miyazaki R, Tomita H. A study of the efficacy of keihito for diarrhea in children\*. *Kampo no Rinsho (Journal of Kampo Medicine)* 1996; 43: 217-23 (in Japanese).

**1. Objectives**

To determine the efficacy of keihito (啓脾湯) for diarrhea in children.

**2. Design**

Quasi-randomized controlled trial (quasi-RCT).

**3. Setting**

Two clinics, Japan.

**4. Participants**

Thirty-four children (25 boys and 9 girls; age, 4 months – 12.5 years; weight, 7 – 32 kg) with diarrhea that did not respond to 4-day treatment with intestinal remedies (albumin tannate, multidrug-resistant lactobacillus preparation, and loperamide hydrochloride) followed by fosfomycin (50 mg/kg/day) plus antipyretics as needed.

**5. Intervention**

Arm 1: treatment with TSUMURA Keihito Extract Granules (啓脾湯) 1.5–2.0 g/10 kg/day (n=18).

Arm 2: treatment with western medicines (control group; n=16).

**6. Main outcome measures**

Rate of relief of diarrhea, rate of improvement in appetite, and mean number of days to diarrhea resolution.

**7. Main results**

Mean number of days to diarrhea resolution was significantly lower in arm 1 (6.6±2.0 days) than in arm 2 (8.2±1.7 days) ( $P<0.05$ ). Rates of relief of diarrhea and improvement in appetite were not significantly different between arms 1 and 2.

**8. Conclusions**

For children with diarrhea unresponsive to 4-day treatment with the usual western medicines, keihito is an effective prescription inasmuch as it reduces the number of days to diarrhea resolution.

**9. From Kampo medicine perspective**

After the completion of the study, retrospective evaluation of responders and non-responders in the keihito group revealed that two non-responders had residual cold symptoms including fever and were not considered to have *tai-in-byo* (太陰病, greater yin disease) *kyo-sho* (虚証, deficiency pattern).

**10. Safety assessment in the article**

None.

**11. Abstractor's comments**

Diarrhea in children can be classified roughly into disease caused by viral or bacterial infection and disease resulting from noninfectious causes such as hypersensitivity to foods and enzyme abnormalities. Most cases are caused by viral infections. For this type of disease, western medicine is not specific and Kampo therapy might be indicated. In the present study, prespecified exclusion of children with bacterial infection, which increases the risk of severe disease, is appreciated. Some problems remain, such as the lack of identification of the cause of diarrhea in participants, the wide variation in age and weight, and the lack of an assessment of safety. In addition, medical economics evaluation would make the study more interesting.

**12. Abstractor and date**

Arai M, 17 October 2008, 1 June 2010, 31 December 2013.