

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

Shiraki K, Tanimoto K, Togashi T, et al. A study of the efficacy of shosaikoto in children with HBe antigen-positive chronic hepatitis B*. *Shonika Rinsho (Japanese Journal of Pediatrics)* 1991; 44: 2146–51 (in Japanese).

Shiraki K, Tanimoto K. Clinical Evaluation of the efficacy of TSUMURA Shosaikoto in children with chronic hepatitis B*. *Dai 7-kai Nihon Shoni Toyo Igaku Kenkyukai Koen Kiroku (Proceedings of the 7th meeting of the Japan Pediatric Society for Oriental Medicine)* 1991; 7: 18–22 (in Japanese)

1. Objectives

To evaluate the efficacy and safety of shosaikoto (小柴胡湯) in the treatment of HBe antigen-positive children with chronic hepatitis B.

2. Design

Randomized controlled trial (RCT).

3. Setting

Nine university hospitals, Japan.

4. Participants

Forty-three HBe antigen-positive children with chronic hepatitis B.

5. Intervention

Arm 1: TSUMURA Shosaikoto (小柴胡湯) Extract Granules was administered before breakfast and dinner according to age (n=23).

Arm 2: no treatment (n= 20).

Follow-up was 6–24 months; mean treatment duration was 18.6 ± 5.5 months.

6. Main outcome measures

Hepatic function test and effect on the HBe antigen-antibody system (SC: seroconversion, SN: seronegative).

7. Main results

ALT and AST levels tended to progressively decrease from the baseline in arm 1 but not to change in arm 2. The percentage of patients with SC or SN at Month 6, Month 12, and final follow-up was 30.4%, 34.8%, and 43.5% in arm 1, and 5.0%, 10.0%, and 25.0% in arm 2, respectively. The percentage of patients with SC at Month 6, Month 12, and final follow-up was 17.4%, 17.4%, and 30.4% in arm 1, and 0%, 10.0%, and 20.0% in arm 2, respectively.

8. Conclusions

Shosaikoto improves hepatic function and promotes SC from HBe antigen to anti-HBe antibody in children with chronic hepatitis B.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

One patient treated with shosaikoto had epigastric discomfort.

11. Abstractor's comments

It is admirable that a multicenter RCT was conducted and showed the efficacy and safety of shosaikoto in children with chronic hepatitis B. Interestingly, hepatic function was normalized in all patients with SC in the shosaikoto group. The result of a statistical between-group comparison will provide stronger evidence.

12. Abstractor and date

Kogure T, 8 August 2008, 12 October 2011, 31 December 2013.