11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

Reference

Hirayama C, Okumura M, Tanikawa K, et al. A multicenter randomized controlled clinical trial of Shosaiko-to in chronic active hepatitis. Analysis of serum enzyme activities. *Kan-Tan-Sui* 1992; 25: 551–8 (in Japanese). Ichushi Web ID: 1993125235

1. Objectives

To evaluate the efficacy of shosaikoto (小柴胡湯) in the treatment of chronic active hepatitis.

2. Design

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

3. Setting

Forty-two institutions.

4. Participants

Two hundred and twenty-two patients who were diagnosed with chronic active hepatitis based on liver biopsy within a year of symptom onset: 123 patients with non-B hepatitis and 99 patients with hepatitis B.

5. Intervention

Arm 1: Kanebo Shosaikoto (小柴胡湯) Extract Fine Granules (containing 0.9 g of shosaikoto extract/g) 7.5 g t.i.d. for 12 weeks (n=110).
Arm 2: Placebo (containing 0.5 g of shosaikoto extract/g) 7.5 g t.i.d. for 12 weeks (n=106).

6. Main outcome measures

Subjective symptoms and hepatic function tests (absolute value, %, and improvement rated on a 7-grade scale).

7. Main results

Serum aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels were significantly lower in arm 1 than in arm 2 and significantly decreased from baseline in arm 1 at Week 12 ($P<0.05$). There was no significant between-arm difference in γ-glutamyltranspeptidase (γ-GTP) which remained unchanged from baseline in arm 1. Improvement in ALT but not AST or γ-GTP was significantly greater in arm 1 ($P<0.05$).

8. Conclusion

Shosaikoto decreases serum AST, ALT, and LDH in chronic hepatitis.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Dropouts (12 patients in the shosaikoto group and 6 patients in the placebo group) were described, but no adverse drug reactions were documented.

11. Abstractor's comments

It is admirable that a multicenter, placebo-controlled DB-RCT was conducted. The clinical significance would be further enhanced by documentation of liver histology and longer-term outcome.

12. Abstractor and date

Kogure T, 8 August, 2008, 1 June 2010.