11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

References

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Hirayama C, Okumura M, Tanikawa K, et al. A multicenter randomized controlled clinical trial of shosaiko-to in chronic active hepatitis. *Kan-Tan-Sui* 1990; 20: 751–9 (in Japanese). Ichushi Web ID: 1991006763

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

1. Objectives

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

2. Design

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

3. Setting

Seven university hospitals and 31 general hospitals, Japan.

4. Participants

Two hundred and twenty-two patients who were diagnosed with chronic active hepatitis based on liver biopsy within a year of the onset of symptoms.

5. Intervention

Arm 1: Kanebo Shosaikoto (小柴胡湯) Extract Fine Granules (containing 0.9 g of shosaikoto extract/g) at a dose of 1 pack (2.0 g) t.i.d. for at least 12 weeks (n=116).

Arm 2: placebo fine granules (containing 0.09 g of shosaikoto extract/g) at a dose of 1 pack (2.0 g) t.i.d. for 12 weeks (n=106).

6. Main outcome measures

Hepatic function test (absolute value, %), presence of HBe antigen and anti-HBe antibody.

7. Main results

Aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels were significantly decreased in arm 1 at Week 12, but were almost comparable between arm 1 and arm 2 at Week 24. There was no significant difference between arms for γ-GT. By percentage decrease from the previous values, AST and ALT decreased significantly in the shosaikoto group after 12 weeks ($P<0.05$); however, there was no difference between groups for γ-GT. In arm 1 and arm 2, respectively, 4 of 27 patients and 5 of 32 patients became HBe antigen-negative, and 3 of 26 patients and 2 of 33 patients became anti-HBe antibody-positive. No significant between-arm difference was observed.

8. Conclusions

Shosaikoto significantly improves abnormal hepatic function compared with placebo.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Ten and 3 patients had adverse drug reactions to shosaikoto and placebo, respectively. Adverse drug reactions to shosaikoto requiring discontinuation of treatment were reported in 4 patients (general malaise [1 patient]; nausea [1 patient]; diarrhea [1 patient]; numbness of tongue [1 patient]). However, urinalysis results or blood pressure remained unchanged during the study.

11. Abstractor's comments

It is admirable that a multicenter DB-RCT was conducted. I consider that the efficacy of shosaikoto (24-month follow-up) was objectively evaluated. It is clinically significant that shosaikoto improved abnormal hepatic function more markedly in cases of hepatitis B, and was more effective in histologically mild disease.

12. Abstractor and date

Kogure T, 8 August 2008, 31 December 2013, 76June 2015.