Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

Reference

Sasaki D, Sudoh T, Kunikane M, et al. Usefulness of Kanebo Saireito Extract Fine Granules for chronic hepatitis - a comparative study (with randomization carried out using the sealed-envelope method) -*. *Progress in Medicine* 1989; 9: 2923–37 (in Japanese). Ichushi Web ID: 1991131916

1. Objectives

To evaluate the efficacy and safety of saireito (柴苓湯) in the treatment of chronic hepatitis.

2. Design

Randomized controlled trial (envelope method) (RCT-envelope).

3. Setting

One university hospital and 20 general hospitals, Japan.

4. Participants

Hundred patients who were clinically diagnosed with chronic hepatitis.

5. Intervention

Arm 1: Kanebo Saireito (柴苓湯) Extract Fine Granules 2.7 g t.i.d. for 12 weeks (n=53). Arm 2: Proheparum 2 tablets t.i.d. for 12 weeks (n=47).

6. Main outcome measures

Hepatic function test, HBsAg level, physical findings (hepatomegaly, etc.), subjective symptoms, hematology/biochemistry, and improvement in each measure rated on a 5-grade scale. Safety was considered a measure of overall usefulness.

7. Main results

Eighty-eight patients were included in the analyses. No significant between-group difference was observed in glutamic-oxaloacetic transaminase (GOT), glutamic-pyruvic transaminase (GPT), γ -glutamyl transpeptidase (γ -GTP), alkaline phosphatase (ALP), cholinesterase (ChE), zinc sulfate turbidity test (ZTT), total bilirubin, total cholesterol, triglyceride (TG), total protein (TP), albumin, or hepaplastin test (HPT). . Global improvement and usefulness were significantly greater in the saireito group (P<0.05).

8. Conclusions

It is suggested that saireito is useful in the treatment of chronic hepatitis.

9. From Kampo medicine perspective None.

10. Safety assessment in the article

In the saireito group, 1 patient had dizziness and fatigability, 1 patient had anemia, and 3 patients had nausea.

11. Abstractor's comments

It is admirable that a multicenter RCT was conducted. However, caution should be used in the clinical interpretation of the usefulness and global improvement results, since these measures are not frequently evaluated. The authors stated that marked improvement was achieved in patients with high GOT and/or GPT in the saireito group.

12. Abstractor and date

Kogure T, 8 August, 2008, 1 June 2010, 31 December 2013.