11. Diseases of the Digestive Syestem

Reference

Hong SH, Kwon OS, Kim SH et al. Effects of Injinoryung-San on alcoholic hepatitis. *Dongui-Saengli-Byeongli-Hakhoeji* (*Korean Journal of Oriental Physiology & Pathology*) 2008; 22(1): 204–8 (in Korean with English abstract).

1. Objectives

To evaluate the effect of Injinoryung-san (茵蔯五苓散) on alcoholic hepatitis.

2. Design

Double-blinded randomized controlled trial (DB-RCT).

3. Setting

Two Oriental hospitals (Daejeon Oriental Hospital and Oriental Medicine Hospital of Dongeui Universtiy), Republic of Korea.

4. Participants

Thirty-one male subjects who drank more than once a week and 40 g a day (age range, 20–70) with elevated serum aspartate transaminase (AST), alanine transaminase (ALT), and gamma-(γ)-glutamyl transferase (GGT) levels and no clinical findings of hepatoma, hepatic cirrhosis, viral hepatitis, drug-induced hepatitis, and metabolic disorders by abdominal ultrasonography.

5. Intervention

Arm 1: Injinoryung-san (茵蔯五苓散) treatment for 2 weeks.

Arm 2: Placebo control treatment for 2 weeks.

During the study, 4 subjects were excluded from the efficacy evaluation (2 for violation of inclusion/exclusion criteria, 1 for violation of drug intake restrictions, and 1 for insufficient adaptability). Twenty-seven subjects (15 in Arm 1, 12 in Arm 2) were finally included for analysis.

6. Main outcome measures

Abdominal ultrasonography findings, blood biochemistry including serum levels of AST, ALT and GGT, and mean cell volume (MCV) 2 , 4, and 6 weeks after treatment. Changes in body composition before and after treatment.

7. Main results

There were no between-group differences in AST, ALT, and AST/ALT. But GGT level after 2 weeks, MCV and GGT level after 4 weeks, and MCV after 6 weeks were significantly lower in Arm 1 than in Arm 2.

8. Conclusions

Injinoryung-san (茵蔯五苓散) may have a partial effect on alcoholic hepatitis.

9. Safety assessment in the article

Hangover symptoms the day after treatment and a skin rash on both thighs developed in one patient in Arm 1. The symptoms were thought to be drug-related and disappeared a week after the end of treatment. Hepatic dysfunction became worse in one patient in Arm 1, but this patient failed to attend his follow up visit. In laboratory tests, all values were within normal range.

10. Abstractor's comments

In this study, the treatment period was short and many patients dropped out before the end of the study. A search for new Oriental drug candidates for treating alcoholic hepatitis is needed.

11. Abstractor and date

Cho JH, 16 July 2010.