18. Symptoms and Signs

Reference

Nishizawa Y, Nishizawa Y, Amemori Y, et al. A randomized paralleled group comparison in multicenter cooperation: analgesic effect and safety with gosha-jinki-gan and shakuyaku-kanzo-to in the treatment of painful muscle cramps in patients with cirrhosis. *Itami to Kampo* (*Pain and Kampo Medicine*) 2000; 10: 13-8 (in Japanese with English abstract). Ichushi Web ID: 2002242334

1. Objectives

To evaluate the efficacy and safety of shakuyakukanzoto (芍薬甘草湯) for muscle cramps in the calves.

2. Design

Randomized controlled trial (RCT).

3. Setting

Not mentioned, Japan.

4. Participants

Seventy-five patients with painful muscle cramps in the calves (PMC) associated with hepatic cirrhosis.

5. Intervention

Arm 1: oral administration of TSUMURA Goshajinkigan (牛車腎気丸) Extract Granules (GJG) 30 mg/kg t.i.d. for 12 consecutive weeks, n=38.

Arm 2: oral administration of 50 mg/kg/day of TSUMURA Shakuyakukanzoto (芍薬甘草湯) Extract Granules (SKT) in 3 divided doses for 12 consecutive weeks, n=37.

6. Main outcome measures

PMC rating (overall QOL, visual analog scale pain [VAS-P], face rating scale), QOL (modified health assessment questionnaire [MHAQ]), overall well-being (quality of well-being score), and psychological well-being (face scale).

7. Main results

GJG was significantly superior to SKT in improving the PMC rating and various QOL measures. The number of days until resolution of PMC was significantly shorter in the GJG group than in the SKT group.

8. Conclusions

Goshajinkigan is effective and safe for PMC associated with hepatic cirrhosis and is superior to shakuyakukanzoto in efficacy.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Adverse drug reaction symptoms and laboratory test abnormalities (increased AST, LDH, and CPK) were noted in 0 patients receiving goshajinkigan and 4 patients receiving shakuyakukanzoto, but these resolved after discontinuation of treatment.

11. Abstractor's comments

This paper suggests that goshajinkigan may be the first-choice drug for PMC associated with hepatic cirrhosis.

12. Abstractor and date

Kogure T, 15 June 2007, 1 April 2008.