18. Symptoms and Signs

Reference

Yoshida M, Kitaoka H, Masui Y, et al. Effects of shakuyaku-kanzo-to on muscle cramp in diabetics. *Shinkei Chiryogaku* (*Neurological Therapeutics*) 1995; 12: 529-34 (in Japanese).

1. Objectives

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

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

One university hospital and multiple general hospitals, Japan.

4. Participants

Fifteen patients with non-insulin-dependent diabetes mellitus (NIDDM) in relatively good glycemic control who complained of muscle cramps two or more times a week.

5. Intervention

Arm 1: treatment with shakuyakukanzoto (芍薬甘草湯) extract granules (manufacturer, not specified) 7.5 g/day for 4 weeks (n=10).
Arm 2: treatment with eperisone hydrochloride 150 mg/day for 4 weeks (n=5).
Patients were followed up for 4 weeks after the completion of treatment; total follow-up period was 10 weeks.

6. Main outcome measures

Muscle cramps: improvement in frequency of muscle cramps was rated on a 5-point scale based on the post-treatment/pre-treatment ratio of the frequency; improvement in severity of muscle cramps was rated on a 5-point scale based on the change in pain scores (on a 4-point scale).

7. Main results

The improvement in the frequency of muscle cramps was “marked” in 20%, “moderate” in 70%, and “mild” in 10% for arm 1, and “moderate” in 60% and “no change” in 40% for arm 2. The improvement in the severity of muscle cramps was “marked” in 10%, “moderate” in 40%, “mild” in 30%, and “no change” in 20% for arm 1, and “mild” in 40% and “no change” in 60% for arm 2.

8. Conclusions

Shakuyakukanzoto is effective for preventing muscle cramps in diabetic patients and its efficacy is comparable or superior to that of eperisone hydrochloride.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse drug reactions occurred in shakuyakukanzoto-treated patients.

11. Abstractor’s comments

It is clinically significant that a multicenter RCT was attempted, although the sample size was small. However, the between-group comparison of improvement was insufficient. As for adverse drug reactions, the number of patients analyzed was limited in this study and therefore reevaluation in a larger population is desired.

12. Abstractor and date

Kogure T, 8 August 2008.