

6. Nervous System Diseases (including Alzheimer's Disease)**References**

Kimura H, Otake T, Ishikura H. Efficacy of shakuyakukanzoto for relieving facial spasm*. *Shindan to Chiryō (Diagnosis and Treatment)* 1991; 79: 2505–8 (in Japanese).

1. Objectives

To evaluate the efficacy of shakuyakukanzoto (芍薬甘草湯) for relieving facial spasm.

2. Design

Randomized controlled trial (RCT).

3. Setting

Outpatient department of anesthesia of one hospital, Japan.

4. Participants

Twenty patients visiting hospital with facial spasm (3 males and 17 females; mean age, 58.3 years), all receiving a centrally-acting muscle relaxant (afloqualone, tolperisone hydrochloride, and tizanidine hydrochloride in 15, 3 and 2 patients, respectively) and minor tranquilizer (diazepam and etizolam in 11 and 9 patients, respectively).

5. Intervention

Arm 1: administration of TSUMURA Shakuyakukanzoto (芍薬甘草湯) Extract Granules 7.5 g/day in 9 patients and 5.0 g/day in 1 patient (2 males and 8 females).

Arm 2: no administration of shakuyakukanzoto (芍薬甘草湯) (1 male and 9 females).

6. Main outcome measures

Severity of spasm rated before and 4, 8, 12, and 16 weeks after the start of treatment on a 4-point scale (disappeared, rare, repetitive, persistent).

7. Main results

There was no difference in baseline severity between arms. The severity in both arms decreased with time resulting in no significant between-arm differences at 4 and 8 weeks and significantly larger decrease in severity in arm 1 at 12 and 16 weeks (12 weeks, $P<0.05$; 16 weeks, $P<0.05$).

8. Conclusions

Combination of shakuyakukanzoto with a centrally-acting muscle relaxant and minor tranquilizer significantly decreases severity of facial spasm.

9. From Kampo medicine perspective

The authors state that “shakuyakukanzoto can be used without considering *sho* (証, pattern), which should be usually taken into account in prescribing a Kampo formulation, suggesting its usefulness for facial spasma.”

10. Safety assessment in the article

No adverse drug reactions suspected to be attributable to shakuyakukanzoto occurred.

11. Abstractor's comments

First, this study is respectable for conducting an RCT of a Kampo medicine in 1991, when the term evidence-based medicine had only just emerged. From the perspective of CONSORT statement, however, this study raises some concerns; the drugs and their doses differed between arms, suggesting that the study may have been biased. It is not known whether the study was blinded. A study with a more rigorous design to re-evaluate efficacy is expected.

12. Abstractor and date

Tsuruoka K, 23 September 2008, 1 June 2010, 31 December 2013.