

18. Symptoms and Signs

Reference

Takao Y, Takaoka Y, Sugano A, et al. Shakuyaku-kanzo-to (Shao-Yao-Gan-Cao-Tang) as treatment of painful muscle cramps in patients with lumbar spinal stenosis and its minimum effective dose. *Kobe Journal of Medical Sciences* 2015; 61: 5: E132-7. CENTRAL ID: CN-01140769, Pubmed ID: 27363396

1. Objectives

To evaluate the efficacy and safety of shakuyakukanzoto (芍薬甘草湯) for muscle cramps in patients with lumbar spinal stenosis

1. Design

Randomized controlled trial (RCT)

2. Setting

One university hospital, Japan

3. Participants

Thirty patients with lumbar spinal stenosis

4. Intervention

Arm 1: Oral administration of TSUMURA Shakuyakukanzoto (芍薬甘草湯) Extract Granules 7.5 g (in 3 divided doses)/day for 2 weeks (n=16)

Arm 2: Oral administration of eperisone hydrochloride (dose not specified) for 2 weeks (n=14)

5. Main outcome measures

Frequency of muscle cramps at Week 2 of treatment. Time to maximum therapeutic response.

6. Main results

The frequency of muscle cramps decreased to $\leq 50\%$ in 14 (87.5%) of the 16 patients in Arm 1, compared with 4 (28.6%) of the 14 patients in Arm 2. Maximum therapeutic response was achieved within 3 days in $\geq 50\%$ of the patients in Arm 1.

7. Conclusions

The results suggest that shakuyakukanzoto is effective for muscle cramps in lumbar spinal stenosis.

8. From Kampo medicine perspective

None.

9. Safety assessment in the article

Dizziness was reported in an 80-year-old man with a history of cerebral infarction, and improved after discontinuation of shakuyakukanzoto. No other adverse events were noted.

10. Abstractor's comments

This study evaluated the efficacy and safety of shakuyakukanzoto, compared with eperisone hydrochloride, for muscle cramps in patients with underlying lumbar spinal stenosis. Although the article states that the study consisted of 3 arms (i.e., the above-stated two arms plus Arm 3 [n=28] to determine the minimum effective dose) and was conducted in a total of 58 patients who were randomized to these 3 arms, this randomization to Arm 3 was not further described. Furthermore, regarding the use of a chi-square test for intergroup comparison stated in Figure 2, it is unclear which groups were compared. In addition, it is questionable whether ANOVA used in Figure 3 was an appropriate statistical method. While there have been other reports on the efficacy of shakuyakukanzoto for muscle cramps, this is the first report to specifically evaluate it in patients with lumbar spinal stenosis. Thus, further clinical studies with sufficient sample size and scientifically valid design are warranted.

11. Abstractor and date

Motoo Y, 18 May 2020