

4. Metabolism and Endocrine Diseases

Reference

Muramatsu N, Okayasu M. Clinical study on hyperlipidemia at bezafibrate and da-chai-hu-tang (dai-saiko-to) for the combination therapy (Clinical study of hyperlipidemia after combination therapy with bezafibrate and da-chai-hu-tang (dai-saiko-to)). *Shigaku (Odontology)* 1993; 81: 94-9 (in Japanese with English abstract).

1. Objectives

Efficacy and safety of daisaikoto (大柴胡湯) combined with bezafibrate in patients with hyperlipidemia.

2. Design

Randomized controlled trial (RCT).

3. Setting

One university hospital, Japan.

4. Participants

Ten patients with hyperlipidemia (mean age, 55.4 years) (3 with type IIa and 7 with type IIb according to WHO classification, and 4 with *jitsu-sho* [実証, excess pattern] and 6 with *chukan-sho* [中間証, intermediate pattern]).

5. Intervention

Arm 1: combination of TSUMURA Daisaikoto (大柴胡湯) Extract Granules 7.5 g/day and bezafibrate 400 mg/day for 12 weeks (n=5).

Arm 2: bezafibrate 400 mg/day for 12 weeks (n=5).

6. Main outcome measures

Total cholesterol (TC) and triglyceride (TG) were measured every 4 weeks and their rate of decline was calculated.

7. Main results

The rate of decline in TC was not different between arms and that in TG tended to be greater in arm 1 than arm 2.

8. Conclusions

Daisaikoto (大柴胡湯) enhances the blood TG-lowering effect of bezafibrate.

9. From Kampo medicine perspective

Deficiency-Excess Pattern Identification according to *jitsu-sho* score was adopted as a patient characteristic; 3 and 1 patient in arm 1, and 1 and 4 patients in arm 2, had *jitsu-sho* and *chukan-sho*, respectively. However, the article does not discuss *sho* (証, pattern).

10. Safety assessment in the article

No adverse reaction was observed.

11. Abstractor's comments

This study compared the efficacy of bezafibrate monotherapy with that of bezafibrate and daisaikoto combination therapy. For lowering TG, the combination therapy may be more effective than monotherapy; however, this study was small and no statistical analysis was performed. Since there are few effective agents for lowering TG by a mechanism of action different from that of bezafibrate, investigation of combination therapy with such agents (e.g., daisaikoto) would be meaningful. Studies with larger sample size are needed.

12. Abstractor and date

Namiki T, 29 December 2008, 1 June 2010.