4. Metabolism and Endocrine Diseases

Reference

Sasaki J, Matsunaga A, Handa K, et al. Effect of daisaikoto on hyperlipidemia - comparison with clinofibrate -*. *Rinsho to Kenkyu* (*Japanese Journal of Clinical and Experimental Medicine*) 1991; 68: 3861-71 (in Japanese). Ichushi Web ID: 1992128245

1. Objectives

To evaluate the efficacy and safety of daisaikoto (大柴胡湯) in patients with hyperlipidemia.

2. Design

Randomized controlled trial (RCT).

3. Setting

University hospitals and community hospitals, Japan.

4. Participants

Sixty patients with fasting serum total cholesterol ≥ 220 mg/dl and/or triglyceride ≥ 150 mg/dl.

5. Intervention

Arm 1: administration of TSUMURA Daisaikoto (大柴胡湯) Extract Granules 2.5 g t.i.d. for 16 weeks (n=27).
Arm 2: administration of clinofibrate 200 mg t.i.d. for 16 weeks (n=18).
Arm 3: administration of TSUMURA Daisaikoto (大柴胡湯) Extract Granules 2.5 g t.i.d. plus clinofibrate 200 mg t.i.d. for 16 weeks (n=15).

6. Main outcome measures

Levels of serum lipids (including total cholesterol, LDL cholesterol, HDL cholesterol, and serum triglyceride), and apoprotein.

7. Main results

There was a significant reduction in serum triglyceride (P<0.05), apo A-1 (P <0.05), apo E (P <0.05), and lipid peroxide (P<0.01) in the daisaikoto monotherapy group. In contrast, there was no significant change in the clinofibrate monotherapy and clinofibrate with daisaikoto groups.

8. Conclusions

Daisaikoto monotherapy was effective for hyperlipidemia.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Although no patient had severe adverse effects, five had diarrhea and loose stool, one had tachycardia and menorrhagia, and one had the elevation of γ-GTP level in the daisaikoto monotherapy group. One in clinofibrate with daisaikoto group had mild adverse effects including diarrhea and abdominal pain.

11. Abstractor's comments

The low follow-up rate (20 of 60 enrolled patients dropped out of the study, leaving only 40 included in the analysis) is a limitation of this study.

12. Abstractor and date

Namiki T, 29 December 2008, 6 January 2010, 31 December 2013.