

#### 4. Metabolism and Endocrine Diseases

##### Reference

Yamano S, Sawai F, Hashimoto T, et al. Comparative effects between dai-Saiko-to and elastase on lipid metabolism and cerebral circulation in patients with hyperlipidemia. *Kampo to Saishin-chiryō (Kampo & The Newest Therapy)* 1995; 4: 309-13 (in Japanese).

##### 1. Objectives

To evaluate the effects of daisaikoto (大柴胡湯) on serum lipid level and cerebral circulation.

##### 2. Design

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

##### 3. Setting

One university hospital, Japan.

##### 4. Participants

Sixty-five outpatients with hyperlipidemia (i.e., serum cholesterol  $\geq$  200 mg/dL or serum triglyceride  $\geq$  150 mg/dL) on 3-month diet therapy.

##### 5. Intervention

Arm 1: administration of TSUMURA Daisaikoto (大柴胡湯) Extract Granules 2 g t.i.d. for 12 months (n=27).

Arm 2: administration of elastase 5,400 elastase unit (EL.U.) per day for 12 months (n=38).

Arm 3: healthy controls matched for age and sex (n=27).

##### 6. Main outcome measures

Determination of serum lipids (including total cholesterol [TC], high density lipoprotein-cholesterol [HDL], and triglyceride [TG] levels) before treatment and after 6 and 12 months.

Hemodynamic parameters in the common carotid artery were also measured.

##### 7. Main results

In within-group comparisons, in arm 1, TC and TG levels decreased significantly after 6 and 12 months and HDL level increased significantly after 12 months, relative to baseline (pretreatment level). In arm 2, TC and HDL showed no change but TG decreased significantly. In between-group comparisons, improvement in TC was greater in the daisaikoto arm than the elastase arm ( $245.2 \pm 64.5$  ng/dL vs.  $228.5 \pm 48.7$  ng/dL), whereas between-arm improvements in HDL and TG were similar. Hemodynamic parameters of the common carotid artery, blood pressure, and heart rate were unaffected in both arms.

##### 8. Conclusions

In patients with hyperlipidemia, daisaikoto and elastase improves serum cholesterol but not cerebral circulation. The effect of daisaikoto is greater than that of elastase.

##### 9. From Kampo medicine perspective

None.

##### 10. Safety assessment in the article

None.

##### 11. Abstractor's comments

The control group consisted of healthy subjects (matched for age and sex). This study was therefore a randomized controlled trial with two arms.

##### 12. Abstractor and date

Namiki T, 29 December 2008, 1 June 2010.