

21. Others

Reference

Fukushima M. Profiles of effects of traditional oriental herbal medicines on the central nervous system in humans - assessment of saiboku-to and saiko-ka-ryukotsu-borei-to using EEG and pharmacokinetics of herbal medicine-derived ingredients as indices -. *Seishin Shinkeigaku Zasshi (Psychiatria et Neurologia Japonica)* 1997; 99: 355-69 (in Japanese with English abstract).

1. Objectives

To evaluate the effects of saibokuto (柴朴湯) and saikokaryukotsuboreito (柴胡加竜骨牡蛎湯) on the central nerve system in humans.

2. Design

Randomized controlled trial (RCT).

3. Setting

Single-center study in Department of Neuropsychiatry, Kansai Medical University, Japan.

4. Participants

Twelve healthy adult men.

5. Intervention

Arm 1: TSUMURA Saibokuto (柴朴湯) Extract Granules 7.5 g q.d. for 1 day followed by 2.5 g t.i.d. for 8 days.

Arm 2: TSUMURA Saikokaryukotsuboreito (柴胡加竜骨牡蛎湯) 7.5 g q.d. for 1 day and 2.5 g t.i.d. for the following 8 days

Arm 3: lactose (placebo) 3 g q.d. for 1 day followed by 2.5 g t.i.d. for 8 days.

There was a washout period of 2 weeks or more between treatments.

6. Main outcome measures

Electroencephalogram (EEG) global field power (GFP) spectrum change.

7. Main results

For each individual, placebo-controlled data on GFP were used to calculate change due to treatment (i.e., the difference in GFP between before and after treatment). In Arm 1, there was an increase of 3.24 in the δ band 1 hour after administration ($P<0.01$) and an increase of 3.20 in the α_3 band 3 hours after administration ($P<0.01$). In Arm 2, there was no significant change in GFP 1, 3, or 6 hours after administration.

8. Conclusions

Saibokuto may have an effect on the central nervous system.

9. From Kampo medicine perspective

Mentioned in section "Subjects and Administration Method".

10. Safety assessment in the article

Not documented.

11. Abstractor's comments

In this article, saibokuto changed the EEG global field power in healthy adult men. This indicates that the GFP may be used as an objective measure of the central effect of saibokuto. In addition, the authors stated that the response to saibokuto varied among individuals. Further studies based on *sho* (証, pattern.syndrome) are awaited to validate the results of this study.

12. Abstractor and date

Okabe T, 29 August 2008, 1 June 2010, 31 December 2013.