

9. Cardiovascular Diseases

Reference

Ito E, Takahashi A, and Kazuya F. Clinical effectiveness of TSUMURA Orengedokuto in the treatment of cerebral infarction. *Geriatric Medicine* 1991; 29: 303-13 (in Japanese).* Ichushi Web ID: 1991179676

1. Objectives

To evaluate the efficacy and safety of orengedokuto (黄連解毒湯) in the treatment of cerebral infarction.

2. Design

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

3. Setting

Fifteen hospitals (two departments of a university hospital and 14 hospitals), Japan.

4. Participants

A total of 109 clinically stable patients with cerebral infarction (thrombosis, embolism) (57 men and 51 women, and 1 patient who withdrew consent).

5. Intervention

Arm 1: administration of Tsumura Orengedokuto (黄連解毒湯) Extract Granules (TJ-15) 2.5 g t.i.d. orally before meals for 12 weeks (n=56).

Arm 2: no administration of Kampo medicines for 12 weeks (n=52).

6. Main outcome measures

Overall severity, subjective symptoms, neurological symptoms, improvement in activities of daily living (ADL), general improvement, safety, and usefulness were evaluated before administration and 4, 8, and 12 weeks after administration. Clinical parameters were examined (blood pressure, pulse rate, blood count, standard biochemical parameters, blood coagulation and fibrinolytic activity).

7. Main results

No significant changes were observed in overall severity and in general improvement. Patients were evaluated to be "more than slightly improved" in subjective symptoms significantly more frequently in arm 1 than arm 2 ($P<0.05$). Among subjective symptoms, improvement in dull headache, vertigo, hot flashes ($P<0.05$), and cold feeling and numbness of the limbs and stiff shoulders ($P<0.01$) occurred significantly more frequently. Significant change occurred in usefulness ($P<0.05$) but not in mental symptoms, neurological symptoms, and ADL. Significant difference in the clinical parameters was observed only in blood coagulation and fibrinolytic activity.

8. Conclusions

Orengedokuto was suggested to be effective in improving subjective symptoms (hot flashes, headaches, stiff shoulders, and cold feeling and numbness of the limbs) in patients with cerebral infarction.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Adverse effects were observed in 3 patients in arm 1 (lightheadedness or dizziness) and 1 patient in arm 2 (loose stool and vomiting).

11. Abstractor's comments

By around 1990, at the time when this article was published, efficacy of orengedokuto for cerebral infarction had been surmised from basic research, accumulation of clinical cases, and comparison with the other medicines. This is a high-quality controlled-trial demonstrating that orengedokuto improves some of the subjective symptoms in clinically stable patients with cerebral infarction.

Reported pharmacological activities of orengedokuto include increase in local blood flow in the hippocampal region, inhibition of platelet aggregation by baicalein which is a component of ogon (黄芩) present in this Kampo medicine. And these reported activities are consistent with the present study result revealing the improvement in blood coagulation and fibrinolytic activity. They observed no effect on blood pressure, which is also the result of other large-scale trials studying its efficacy against high blood pressure. Therefore, orengedokuto seems to have little effect on decreasing blood pressure.

12. Abstractor and date

Namiki T, 29 December 2008, 6 January 2010, 1 June 2010, 31 December 2013.