

6. Nervous System Diseases (including Alzheimer's disease)**Reference**

Yamada K, Kanba S, Ohnishi K, et al. Clinical effectiveness of oren-gedoku-to for sleep disorder associated with acute schizophrenia and other psychotic disorders. *Nihon Toyo Igaku Zasshi (Japanese Journal of Oriental Medicine)* 1997; 47: 827-31 (in Japanese with English abstract). [CiNii](#)

1. Objectives

To evaluate the efficacy of orengekuto (黄連解毒湯) for sleep disorder associated with acute psychotic disorder.

2. Design

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

3. Setting

No study site was specified (authors belonged to the Kampo Clinic, School of Medicine, Keio University and/or Department of Neuropsychiatry, School of Medicine, Keio University), Japan.

4. Participants

Eighteen untreated male patients who were diagnosed with schizophrenia, schizoaffective disorder, schizophreniform disorder, or brief psychotic disorder according to Diagnostic and Statistical Manual of Mental Disorders (DSM)-IV criteria, and had sleep disorder among their chief complaints.

5. Intervention

Arm 1: standard therapy with haloperidol in combination with oral treatment with TSUMURA Orengekuto (黄連解毒湯) Extract Granules 2.5 g t.i.d. for 4 weeks (n=9).

Arm 2: only standard therapy with haloperidol for 4 weeks (n=9).

6. Main outcome measures

Dose of nitrazepam used as needed for insomnia; assessment of schizophrenic symptoms by the Brief Psychiatric Rating Scale (BPRS).

7. Main results

In assessment of schizophrenic symptoms, there was no between-arm difference. In addition, there was no significant between-arm difference in the oral dose of nitrazepam.

8. Conclusions

In patients with sleep disorder associated with acute schizophrenia and other psychotic disorders, orengekuto used in combination with the antipsychotic tends to improve thought disorder and decrease the dose of nitrazepam.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not documented.

11. Abstractor's comments

This is an interesting clinical study comparing the effect of antipsychotic in combination with orengekuto for sleep disorder associated with acute schizophrenia, etc. with the effect of antipsychotic alone. While it was stated in the Methods section that "in both groups, haloperidol was the only antipsychotic used, and biperiden was the only anti-parkinson agent used", the number of patients treated with each drug was not specified. In addition, it was stated that "the attending physician initiated standard therapy with haloperidol in the presence or absence of concomitant orengekuto", failing to provide information on patients treated with each of these two drugs. Moreover, the statement "tended to improve schizophrenic thought disturbance and decrease the dose of nitrazepam" indicating that there was no significant difference between the orengekuto group and control group, was inconsistent with the statement in the Abstract that "additional treatment with orengekuto may be effective for sleep disorder". Nevertheless, this is a meaningful clinical study in determining the efficacy of Kampo medicine in this field because it suggests the possibility that the efficacy of orengekuto for sleep disorder could be demonstrated by a larger study.

12. Abstractor and date

Goto H, 11 September 2008, 1 June 2010.