

## 12. Skin Diseases

**Reference**

Ohkuma M. Treatment of pruritus by Chinese drugs. *Wakan Iyaku Gakkaishi (Journal of Medical and Pharmaceutical Society for WAKAN-YAKU)* 1993; 10: 126–30 (in Japanese with English abstract).

**1. Objectives**

To evaluate the efficacy of tokiinshi (当帰飲子) and orengedokuto (黄連解毒湯) for the treatment of pruritus.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

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**4. Participants**

One hundred sixty-two patients with pruritus associated with winter eczema, senile crural eczema, asteatotic eczema, and xeroderma. Nineteen patients had diabetes.

**5. Intervention**

Arm 1: oral administration of tokiinshi (当帰飲子) (manufacturer, not specified) + TSUMURA Orengedokuto (黄連解毒湯) Extract Granules 2.5 g t.i.d. after meals (n=68).

Arm 2: oral administration of tokiinshi (当帰飲子) (manufacturer, not specified) 2.5 g t.i.d. after meals (n=49).

Arm 3: TSUMURA Orengedokuto (黄連解毒湯) Extract Granules 2.5 g t.i.d. after meals (n=10).

Arm 4: oral administration of antihistamines (meguitazine 6 mg/day [n=13], terfenadine 120 mg/day [n=4], ketotifen fumarate 2 mg/day [n=14], or oxamide 60 mg/day [n=4]) after meals or at bedtime (n=35).

Treatment duration: at least 4 weeks.

**6. Main outcome measures**

Pruritus was assessed by history taking on a 3-point scale: marked response (disappeared or almost disappeared), moderate response (improved), and no response/worse (not changed or increased).

The observation period was at least 4 weeks. Patients who showed signs of improvement only after more than 4 weeks or stopped visiting within 4 weeks (except those with marked or moderate responses) were counted as dropouts.

**7. Main results**

In arm 1, the response was marked in 25 patients (66%), moderate in 9 (24%), absent or worse in 4 (11%), and there were 30 dropouts. The response in arm 1 was significantly better than that in arm 2 (marked in 39%, moderate in 29%, absent or worse in 32%) and arm 3 (marked in 13%, moderate in 50%, absent or worse in 38%) ( $P<0.05$ ). The response in arm 4 (marked in 37%, moderate in 37%, absent or worse in 26%) did not differ significantly from that in arm 1; however, sleepiness occurred in 6 patients and malaise in 2 in arm 4, while these reactions were not observed in arms 1–3.

**8. Conclusions**

Tokiinshi combined with orengedokuto is as effective as antihistamines for pruritus.

**9. From Kampo medicine perspective**

Tokiinshi is used for *in-kyo* (陰虛, yin deficiency) and orengedokuto is used for *jitsu-you* (実陽, excess yang). These are not usually combined. However, the authors stated that this combination is not irrational, since unseiin (温清飲) is orengedokuto plus shimotsuto (四物湯) (used for *in-kyo*).

**10. Safety assessment in the article**

In arm 4, six patients had sleepiness and two had malaise. In arm 1, two patients experienced stomach fullness.

**11. Abstractor's comments**

This RCT demonstrated the efficacy of tokiinshi combined with orengedokuto for pruritus. In arm 1, 30 of 68 patients dropped out, but the analyses might not have been carried out on an intent-to-treat basis. Clarification of the analyses in this study is expected.

**12. Abstractor and date**

Tsuruoka K, 14 April 2008, 1 June 2010, 31 December 2013.