

## 12. Skin Diseases

**Reference**

Ohkuma M. Treatment of pruritus by Chinese drugs with external application and oral antihistamine. *Wakan Iyakugaku Zasshi (Journal of Traditional Medicines)* 1994; 11: 302–3 (in Japanese).

**1. Objectives**

To compare the efficacy of orengedokuto (黄連解毒湯), tokiinshi (当帰飲子), oral terfenadine (antihistamine), and heparinoid ointment containing peppermint oil monotherapy or combination therapy for the treatment of pruritus.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

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**4. Participants**

Two hundred fifty-one patients with pruritus.

**5. Intervention**

Arm 1: oral administration of orengedokuto (黄連解毒湯) (manufacturer, not specified) + tokiinshi (当帰飲子) (manufacturer, not specified) 2.5 g t.i.d. after meals + terfenadine 60 mg b.i.d. and topical administration of 0.3% heparinoid ointment + 1% peppermint oil (n=44).

Arm 2: oral administration of orengedokuto (黄連解毒湯) (manufacturer, not specified) + tokiinshi (当帰飲子) (manufacturer, not specified) 2.5 g t.i.d. after meals + terfenadine 60 mg b.i.d. (n=72).

Arm 3: oral administration of orengedokuto (黄連解毒湯) (manufacturer, not specified) + tokiinshi (当帰飲子) (manufacturer, not specified) 2.5 g t.i.d. after meals (n=68).

Arm 4: topical administration of 0.3% heparinoid ointment + 1% peppermint oil (n=45).

Arm 5: terfenadine 60 mg b.i.d. (n=14).

Arm 6: 0.3% heparinoid ointment (n=3).

Arm 7: oral administration of orengedokuto (黄連解毒湯) (manufacturer, not specified) + tokiinshi (当帰飲子) (manufacturer, not specified) 2.5 g t.i.d. after meals and topical administration of 0.3% heparinoid ointment + 1% peppermint oil (n=5).

Treatment duration: not mentioned in the article.

**6. Main outcome measures**

The response to treatment was evaluated on a 3-point scale (disappeared or almost disappeared ++, mitigated +, not changed or increased –).

**7. Main results**

The number of cases with responses of ++, +, –, and the number of dropouts were, respectively: 14, 9, 2, and 19 in arm 1; 23, 9, 5, and 35 in arm 2; 25, 9, 4, and 30 in arm 3; 7, 9, 9, and 20 in arm 4; 0, 3, 2, and 9 in arm 5; 0, 1, 1, and 1 in arm 6; 1, 1, 1, and 2 in arm 7. There were significant differences between arms 2 and 4 ( $P<0.05$ ) and 3 and 5 ( $P<0.01$ ) but not between arms 1 and 2, 1 and 3, and 2 and 3.

**8. Conclusions**

Oral administration of orengedokuto, tokiinshi, and terfenadine (antihistamine) and topical administration of heparinoid ointment + peppermint oil (arm 1) is effective for pruritus in the vast majority of cases. The effect of treatment in arm 1 and arm 7 (without antihistamine) is similar.

**9. From Kampo medicine perspective**

The authors stated that combining tokiinshi (used for *kyo-sho* [虚証, deficiency pattern]) with orengedokuto (for *yo-sho* [陽証, yang pattern]) is not irrational, given the fact that unseiin (温清飲) is a combination of orengedokuto (for *yo-sho*) and shimotsuto (四物湯) (for *kyo-sho*).

**10. Safety assessment in the article**

Five patients had difficulty in swallowing in arm 1; 6 had difficulty in swallowing and 1 had dermatitis in arm 2; 5 had difficulty in swallowing in arm 3; 1 had skin warmth in arm 4; none had adverse reactions in arms 5 and 6; 1 had difficulty in swallowing and 3 had bloating in arm 7.

**11. Abstractor's comments**

This RCT compared the efficacy of four agents including Kampo medicines alone or in combination. Basic information including background factors such as underlying disease, age, and sex of participants as well as follow-up period is not provided, making evaluation difficult. Further detailed study is expected.

**12. Abstractor and date**

Tsuruoka K, 17 April 2008, 1 June 2010, 31 December 2013.