

**12. Skin Diseases****Reference**

Shimoda S, Hashizume S, Morita M, et al. Efficacy of TSUMURA Shosaikoto for atopic dermatitis\*. *Hifuka ni okeru Kampo Chiryō no Genkyō (The Current State of Kampo Medicine in Dermatology)* 1991; 2: 15–24 (in Japanese).

**1. Objectives**

To evaluate the efficacy and safety of shosaikoto (小柴胡湯) for treating atopic dermatitis and for withdrawing or tapering topical corticosteroids.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

One university hospital, Japan.

**4. Participants**

Sixty-five atopic dermatitis patients aged 12 years and older, excluding women who were pregnant, possibly pregnant, or lactating.

**5. Intervention**

Betamethasone valerate (0.12% Rinderon V ointment or cream) was used as a topical corticosteroid. During the 8-week observation period, corticosteroids were used as little as possible when improvement in symptoms was observed. Oral corticosteroids were not allowed.

Arm 1: topical corticosteroids + TSUMURA Shosaikoto (小柴胡湯) Extract Granules 2.5 g t.i.d. for at least 8 weeks (n=41).

Arm 2: topical corticosteroids (n=24).

**6. Main outcome measures**

Subjective symptoms: pruritus.

Objective symptoms: papule, erythema, erosion, scales, infiltration, and hypertrophy.

Corticosteroids: could be withdrawn, reduced >50%, or reduced ≤50%.

**7. Main results**

Corticosteroids were withdrawn in two patients in arm 1 and reduced in 87.0% of patients in arm 2 and 62.5% in arm 1.

**8. Conclusions**

Shosaikoto is effective in tapering topical corticosteroid treatment of atopic dermatitis.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Two patients experienced nausea in arm 2.

**11. Abstractor's comments**

Although Kampo medicines have been said to be effective for atopic dermatitis, currently, only the remission of symptoms or withdrawal of topical corticosteroids have been quantitatively assessed. Statistical analyses can not be performed without quantification or scoring of variables such as the severity of skin lesions and objective improvement. Further effort to improve quantification is expected.

**12. Abstractor and date**

Fujisawa M, 13 October 2008, 1 June 2010, 31 December 2013.