

## 12. Skin Diseases

### Reference

Kobayashi H, Yanagihara S, Tamiya H, et al. The combined effects of Kampo medicines on subjective/objective symptoms in atopic dermatitis patients - A comparative study of unseiin and shimotsuto -. *The Nishinippon Journal of Dermatology* 2016; 78: 171-6 (in Japanese). Ichushi Web ID: 2016282808

### 1. Objectives

To evaluate the effectiveness of unseiin (溫清飲) and shimotsuto (四物湯) for moderate or more severe atopic dermatitis that does not improve with standard treatment.

### 2. Design

Randomized controlled trial (envelope method) (RCT-envelope)

### 3. Setting

Single-center (Osaka City University Hospital)

### 4. Participants

Sixteen participants who fulfilled the following conditions between February 2012 and December 2013: 1) diagnosed with atopic dermatitis (AD) according to the Japanese Dermatological Association's diagnostic criteria; 2) currently receiving the standard treatment in the Japanese Dermatological Association's AD treatment guidelines (no change in prescription in the first 2 weeks of the trial) and will continue that treatment during the trial; 3) itch is at least 5 on a visual analog scale (VAS: 0-10).

Patients with infectious disease or severe heart, kidney, or endocrine/metabolic disease, and patients currently taking Kampo or herbal medication were excluded.

### 5. Intervention

Arm 1: Standard treatment and Kracie Unseiin (溫清飲) Extract Fine Granules 6.0g b.i.d. (n=8)

Arm 2: Standard treatment and Kracie Shimotsuto (四物湯) Extract Fine Granules 6.0g b.i.d. (n=8)

As a rule, administration for 4 weeks in both arms. No change of drug or dosage during period of administration.

### 6. Main outcome measures

Kampo medication compliance; subjective symptoms (itch, dryness, sleep disorder evaluated on a VAS); AD severity (measured with severity scoring of AD [SCORAD]); clinical blood tests (serum thymus and activation-regulated chemokine [TARC]; total serum IgE; peripheral eosinophil count, and LDH); specific skin disease QOL scale (Skindex-16: total and sub-scales [symptoms, emotions, functioning]).

### 7. Main results

One participant dropped out of arm 1 (after taking another Kampo medication). Trial drug compliance satisfactory in both arms 1 and 2. Significant improvements in 3 subjective symptoms were observed in arm 1, but no significant improvement was observed in arm 2. VAS score variation between the 2 groups before and after administration showed significant reduction only for dryness in arm 1 ( $P=0.048$ ). SCORAD decreased significantly only in arm 1 before and after administration ( $P<0.05$ ), however, there was no significant difference in arm 2. There was no significant change in either group in clinical test values. Skindex-16 showed significant improvement in total, symptoms, and emotions in arm 1, and total, emotions, and functioning in arm 2. Variation before and after administration was lower in arm 1 than arm 2, but there was no significant difference between groups.

### 8. Conclusions

Unseiin alleviates itch and dryness, and improves QOL in AD, and its effects are superior to shimotsuto.

### 9. From Kampo medicine perspective

None.

### 10. Safety assessment in the article

None.

### 11. Abstractor's comments

This is a clinically significant paper that evaluated in an RCT the effects of unseiin or shimotsuto for AD that had not improved with standard treatment. The 4-week follow-up found more marked improvements in clinical symptoms with unseiin. However, as the authors remark, there was no placebo group for comparison, which unfortunately meant that the study evaluated the effectiveness of the Kampo preparations by before and after comparison. The authors might have obtained greater significant differences in the effects of unseiin and shimotsuto if they had increased the sample size, and they might have gleaned some insights into prescription management. The results of a repeated study with a placebo and larger sample size may be promising.

### 12. Abstractor and date

Kogure T, 18 May 2020.