

12. Skin Diseases

Reference

Wadabayashi M. Kampo Clinical Report: Study on benefits of byakkokaninjinto in treating atopic dermatitis. *Phil Kampo* 2017; 73: 14-5 (in Japanese). Ichushi Web ID: 2019066152

1. Objectives

To evaluate the efficacy and safety of byakkokaninjinto (白虎加人参湯) used concomitantly in the treatment of atopic dermatitis.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

One clinic, Japan.

4. Participants

Twenty-five patients with atopic dermatitis who provided consent to participate in this study and who were newly started on topically applied tacrolimus ointment.

5. Intervention

Arm 1: Tacrolimus ointment application once or twice daily as needed to the affected sites (face and neck) for 2 weeks (n=14).

Arm 2: Tacrolimus ointment application once or twice daily as needed plus KRACIE Byakkokaninjinto (白虎加人参湯) 4 tablets three times daily orally for 2 weeks (n=11).

6. Main outcome measures

Treatment response in the face and neck regions was assessed according to the severity grading criteria of the Japanese Clinical Practice Guideline for the Management of Atopic Dermatitis (simple method). Also, any symptoms of skin irritation associated with the tacrolimus ointment were evaluated at the same time.

7. Main results

Severity was assessed in 13 patients in Arm 1 and 9 patients in Arm 2, because of missing data in 1 patient in Arm 1 and 2 patients in Arm 2. After 2 weeks of treatment, the skin eruption significantly improved in Arm 2. Symptoms of skin irritation associated with the tacrolimus ointment were assessed in 13 patients in Arm 1 and 7 patients in Arm 2, because of missing data in 1 patient in Arm 1 and 4 patients in Arm 2. Within 1 week of treatment, complaints of hot sensation, tingling, or other symptoms of skin irritation were registered by 84.6% of the patients in Arm 1 and 57.1% in Arm 2, showing no statistically significant difference.

8. Conclusions

Although no significant difference was shown, byakkokaninjinto is expected to relieve tacrolimus ointment-related skin irritation symptoms including hot sensation.

9. From Kampo medicine perspective

Not stated.

10. Safety assessment in the article

No side effects were observed in either Arm 1 or Arm 2.

11. Abstractor's comments

This clinical study is interesting in that it demonstrated the potential of byakkokaninjinto for relieving symptoms of tacrolimus ointment-related skin irritation in patients with atopic dermatitis. Tacrolimus ointment-related skin irritation symptoms including hot sensation are troublesome to patients. Byakkokaninjinto was shown to potentially relieve skin irritation symptoms. In this study with a small sample size, the between-group difference was not statistically significant, but a tendency toward relief was observed. Further study results from more patients are awaited.

12. Abstractor and date

Kato Y, 1 September 2019