12. Skin Diseases

Reference

Ito K, Masaki S, Hamada M, et al. Efficacy and safety of the traditional Japanese medicine keigairengyoto in the treatment of acne vulgaris. *Dermatology Research and Practice* 2018: 1-7. CENTRAL ID: CN-01618253, Pubmed ID: 30057596, UMIN ID: UMIN000014831

1. Objectives

To examine the effectiveness and safety of keigairengyoto（荊芥連翹湯）in treating acne vulgaris.

2. Design

Randomized controlled trial (RCT).

3. Setting

Eight hospitals (departments of dermatology), Japan.

4. Participants

Patients aged 15–64 years with acne vulgaris (inflammatory acne) on the face who visited one of the eight facilities between August 2014 and January 2016 and provided consent to participate in this study. For patients under 18 years of age, consent was obtained from their parent or guardian. Exclusion criteria were as follows: (1) severe complications such as liver disease, renal disease, heart disease, blood disease, or metabolic disease; (2) being pregnant, lactating, or planning to become pregnant during the study observation period; (3) taking concomitant medications and research medicines within 1 week before the start of the study; (4) participation in another trial within one month before the initiation of this study; (5) scheduling to undergo a chemical peel or laser therapy during the study observation period; (6) a history of allergies to traditional Japanese medicine; and/or (7) patients for whom, in the opinion of the study scientist or collaborating research doctor, it is not in their best interest to be enrolled in the study. (n=64)

5. Intervention

Arm 1: Conventional topical treatment (adapalene and nadifloxacin or clindamycin) for 12 weeks (n=33).
Arm 2: Conventional topical treatment (adapalene and nadifloxacin or clindamycin) plus TSUMURA Keigairengyoto（荊芥連翹湯） Extract Granules 2.5 g three times daily for 12 weeks (n=31).

6. Main outcome measures

The amount of inflammatory and noninflammatory acne lesions on the face was counted at baseline (study entry) and at weeks 2, 4, 8, and 12. The reduction in this number was calculated for inflammatory, noninflammatory, and all acne lesions.

7. Main results

The efficacy analysis was conducted on 52 patients (28 patients in Arm 1 and 24 patients in Arm 2), after exclusion of 4 patients in Arm 1 and 2 patients in Arm 2. At Weeks 4 and 8, the amount of inflammatory acne lesions significantly decreased in the keigairengyoto combined group ($P<0.05$).

8. Conclusions

Keigairengyoto in combination with conventional treatments may be a useful agent in patients with inflammatory acne.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

There were no serious adverse events in both groups.

11. Abstractor's comments

This clinical study is interesting in that it was designed to determine the effectiveness of keigairengyoto used in the treatment of acne vulgaris. This study suggested that keigairengyoto may be a useful agent in patients with inflammatory acne, and this report may lead to clinical application in the future. Inflammatory acne in the keigairengyoto combined group, compared with the control group, was reported to be significantly improved at Weeks 4 and 8, but not at Week 12. Further study results from more patients are awaited. In addition, studies investigating the effects on inflammatory diseases other than acne vulgaris are desired.

12. Abstractor and date

Kato Y, 1 September 2019.