12. Skin Diseases

Reference

Tanaka M. Effects of oxatomide on urticaria. *Yakuri to Chiryo* (*Japanese Pharmacology and Therapeutics*) 1991; 19:5029–31 (in Japanese).

1. Objectives

Efficacy of kakkonto (葛根湯) as an adjuvant for reducing adverse reactions to oxatomide.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital department of dermatology, Japan.

4. Participants

Fifty-three patients with urticaria.

5. Intervention

Arm 1: oral administration of TSUMURA Kakkonto (葛根湯) Extract Granules 2.5 g t.i.d. before meals for 7 days (n=10).
Arm 2: oral administration of TSUMURA Kakkonto (葛根湯) Extract Granules 2.5 g t.i.d. before meals + oxatomide 30 mg once daily at bedtime for 7 days (n=22).
Arm 3: oral administration of oxatomide 30 mg twice daily, after breakfast and dinner, for 7 days (n=21).

6. Main outcome measures

Itching and wheals were scored separately on a 3-point scale (marked, 2; mild, 1; none, 0). The rates of improvement compared with pre-treatment values were then calculated and classified as marked, moderate, or no response. These classifications were used as scores for the global assessment. The presence of sleepiness was also evaluated.

7. Main results

The rate of improvement was 31.6%, 68.2%, and 68.8% in arms 1, 2, and 3, respectively. For global assessment, the proportion of patients who had at least moderate response was significantly smaller in arm 1 (40%) than in arms 2 and 3 (82% and 76%, respectively, $P<0.05$). No patient in arms 1 and 2 and 10% of patients in arm 3 experienced sleepiness.

8. Conclusions

When oxatomide is used with kakkonto, the dose of oxatomide can be halved to prevent sleepiness.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This was a resourceful clinical trial that evaluated the efficacy of kakkonto as an adjuvant and as a reductant of adverse effects when used with oxatomide for urticaria. However, although the authors stated that the trial was randomized, there was a big between-group difference in the number of patients. In addition, the details of dropouts should be described. Regarding sleepiness, oxatomide was administered at the bedside in arm 2 but not at the bedside (after breakfast and dinner) in arm 3. Of course more marked sleepiness is noticed on awakening in patients in arm 3. For comparison, the drug should have been administered at the bedside in arm 3, too. Daily costs of medication were also compared among the groups and the kakkonto combined therapy was less expensive than oxatomide monotherapy. This clinical study is of interest to general physicians.

12. Abstractor and date

Goto H, 12 September 2008, 1 June 2010.