Task Force for Evidence Reports / Clinical Practice Guideline Special Committee for EBM, the Japan Society for Oriental Medicine

12. Skin Diseases

Reference

Iida T, Nishiyama C, Suzuki H. The effects of toki-inshi and a bath preparation containing licorice extract on patients with senile pruritus. *Nihon Toyo Igaku Zasshi (Japanese Journal of Oriental Medicine)* 1996; 47: 35-41 (in Japanese with English abstract). CiNii

1. Objectives

To evaluate the efficacy of tokiinshi (当帰飲子) combined with a bath preparation containing kanzo (甘 草, licorice) extract in patients with senile xerosis.

2. Design

Randomized controlled trial (RCT).

3. Setting

One special elderly nursing home, Japan.

4. Participants

A total of 25 nursing home residents with xerosis senilis accompanied by senile pruritus, aged from 59 to 92 years, for whom the efficacy of tokinshi is expected (12 men and 13 women). Of these, 19 were included for analysis.

5. Intervention

Arm 1: TSUMURA Tokiinshi (当帰飲子) Extract Granules (TJ-86) 2.5 g t.i.d. before meals for 4 weeks (n=4).

Arm 2: Bath preparation (kanzo extract, jojoba oil, and sodium bicarbonate) 30 g dissolved in 200 L of hot water (39-40°C), and used every other day for 4 weeks (n=5).

Arm 3: TSUMURA Tokiinshi (当帰飲子) Extract Granules (TJ-86) 2.5 g t.i.d. before meals used in combination with bath preparation containing kanzo extract (every other day) (n=4).

Arm 4: no treatment (n=6).

6. Main outcome measures

Degree of skin dryness (water content of the epidermal horny layer) measured using a surface hygrometer (Skicon-200, IBS Company, Hamamatsu, Japan) at baseline and at 7, 14, 21, 18, and 35 days after the start of treatment.

The average values of 3 measurements were compared. Alleviation of pruritus was evaluated by comparing the pruritus score (scale 1-5) at the beginning and the end of the treatment.

7. Main results

The ability of the skin to retain moisture after 21 days of treatment was improved in arm 1 (22.09 \pm 2.27), arm 2 (18.30 \pm 3.01), and arm 3 (17.07 \pm 3.80), but not in arm 4 (5.65 \pm 1.59). In other words, after 3–4 weeks of treatment, the ability to retain moisture increased significantly by 3–5 times in arms 1–3, compared to arm 4 (*P*<0.05 for each). At 35 days (7 days after the treatment was discontinued), the water content of the skin was maintained at high level in arm 1 (16.42 \pm 2.37) and arm 3 (15.97 \pm 3.06) but not in arm 2 (5.57 \pm 0.47), which was almost the same level as that in arm 4 (5.77 \pm 1.29). Alleviation of pruritus did not necessarily correspond to improvement in skin dryness.

8. Conclusions

In patients with xerosis senilis, an oral preparation of tokiinshi, a bath preparation containing kanzo extract, and the combination of both, all improve skin dryness. When used alone, the bath preparation soon loses its effect when the treatment is discontinued. Since improvement in skin dryness does not necessarily alleviate pruritus, involvement of factors other than skin dryness is suggested.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

One patient in arm 4 (no treatment) died during this study (not drug related).

11. Abstractor's comments

A well-designed RCT. In the original article, the study participants were "men and women for whom the efficacy of tokiinshi is expected". However, a detailed explanation of how the enrolled patients were chosen should have been provided. Further studies with larger sample sizes using blind assessment methods are expected.

12. Abstractor and date

Tsuruoka K, 12 April 2008, 6 January 2010, 1 June 2010, 31 December 2013.