Evidence Reports of Kampo Treatment

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

3. Blood Diseases including Anaemia

References

Inagaki M, Nakazawa T, Michimata H, et al. Treatment experience with TSUMURA Keishikajutsubuto for pulmonary sarcoidosis*. Wakan Iyaku Gakkaishi (Journal of Medical and Pharmaceutical Society for WAKAN-YAKU) 1990; 7: 316–7 (in Japanese).

Inagaki M. Effectiveness of Kampo medicine in relieving complaints associated with chronic intractable diseases*. *Kampo Shinryo* 1993; 12: 1–3 (in Japanese)

1. Objectives

To evaluate the effects of Keishikajutsubuto (桂枝加朮附湯) on the levels of angiotensin-converting enzyme and lysozyme in sarcoidosis patients.

2. Design

Randomized controlled trial (RCT).

3. Setting

One university hospital, Japan.

4. Participants

Nine patients with ophthalmic manifestations whose sarcoidosis was confirmed by bronchoscopic lung biopsy. Corticosteroid was used in five of these patients. Chest X-ray showed lymphadenopathy only in six patients, lymphadenopathy and lung field lesions in one, and lung field lesions only in two.

5. Intervention

Keishikajutsubuto (桂枝加朮附湯) was administered for at least 1 year.

Arm 1: TSUMURA Keishikajutsubuto (桂枝加朮附湯) extract granules 2.5 g t.i.d. (n=4).

Arm 2: no treatment (n=5).

6. Main outcome measures

The levels of angiotensin converting enzyme (ACE) and lysozyme.

7. Main results

At the end of the follow-up period, the levels of ACE and lysozyme were decreased in all patients in both arms 1 and 2, including participants using steroids. At the end of the follow-up period, the levels of ACE and lysozyme were decreased in both arms. The decrease in ACE was greater in arm 1. In nonusers of steroids, the decreases in ACE and lysozyme were also greater in arm 1.

8. Conclusions

TSUMURA Keishikajutsubuto, with or without steroids, reduces the levels of ACE and lysozyme in sarcoidosis patients.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No adverse reaction was observed.

11. Abstractor's comments

ACE and lysozyme are referred to as markers for sarcoidosis activity and diagnosis. This paper does not mention improvement on chest X-rays, which suggests there were no changes. Sarcoidosis follow-up takes a long time, so a long-term study with accumulated cases would be more interesting. Furthermore, the sample size in this study was small (four participants in arm 1 and five in arm 2), which makes interpretation of the statistical analysis difficult. Hopefully the authors will conduct an RCT with greater statistical power and an adequate sample size. Inagaki's study (1993) included a large number of cases. Keishikajutsubuto was chosen because sarcoidosis patients often complain of symptoms such as fatigability, cold hands and feet, or joint pain; however, knowing the frequency of such complaints would improve the paper.

12. Abstractor and date

Fujisawa M, 31 March 2009, 1 June 2010, 31 December 2013.