

4. Metabolism and Endocrine Diseases

Reference

Ushiroyama T, Hosotani T, Mori K, et al. Effects of switching to wen-jing-tang (unkei-to) from preceding herbal preparations selected by eight-principle pattern identification on endocrinological status and ovulatory induction in women with polycystic ovary syndrome. *The American Journal of Chinese Medicine* 2006; 34: 177-87. CENTRAL ID: CN-00563518, Pubmed ID: 16552830

1. Objectives

To evaluate the efficacy of switching to unkeito (温経湯) from treatment based on the traditional diagnostic criterion “eight-principle pattern identification” in women with polycystic ovary syndrome (PCOS).

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

3. Setting

Department of Obstetrics and Gynecology, Osaka University Faculty of Medicine, Japan.

4. Participants

Sixty-four patients who visited the outpatient department and were diagnosed with PCOS between 1993 and 2004.

5. Intervention

Sixty-four patients were randomly assigned to one of 2 groups using the diagnostic criterion “*in-yo* (陰陽, yin and yang), *kyo-jitsu* (虚実, excess or deficiency), *hyo-ri* (表裏, interior and exterior), *kan-netsu* (寒熱, cold and heat)” to receive 8-week preliminary administration of either “keishibukuryogan (桂枝茯苓丸)” or “tokishakuyakusan (当帰芍薬散).” Then, 54 non-ovulating patients were further assigned via the RCT-envelope method to receive either a continuation of the same treatment (the continuous treatment group; n = 27) or unkeito (温経湯) (the unkeito group; n = 27) for 8 weeks.

Arm 1: TSUMURA Unkeito (温経湯) Extract Granules 7.5 g/day group, n = 27.

Arm 2: continuous administration group (TSUMURA Keishibukuryogan Extract Granules 7.5 g or TSUMURA Tokishakuyakusan (当帰芍薬散) Extract Granules 7.5 g), n = 27.

6. Main outcome measures

Blood follicle stimulating hormone (FSH), luteinizing hormone (LH), and estradiol (E2) levels and ovulation status.

7. Main results

Switching to unkeito decreased blood LH level and significantly stimulated ovulation.

8. Conclusions

Unkeito has an ovulatory inductive effect, regardless of conventional “*sho*”(証, pattern) identification.

9. From Kampo medicine perspective

Although eight-principle pattern identification is an important criterion for treatment selection, it was not used for the selection unkeito, which was found to stimulate ovulation. Traditional diagnosis based on clinical findings, pathology, and hematology can be an important guide to the selection of Kampo formulae.

10. Safety assessment in the article

No special problems noted.

11. Abstractor’s comments

This paper indicates that switching to unkeito after treatment based on traditional “*sho*” identification improves outcome. The requirement for more objective criteria to make a Kampo diagnosis is extremely important. Other Kampo formulae beside keishibukuryogan and tokishakuyakusan should be considered to treat PCOS. It is of interest to determine whether monotherapy with unkeito would be more effective than monotherapy with other formulae. Future research is expected.

12. Abstractor and date

Nakata H, 10 January 2009, 1 June 2010, 31 December 2013.