

4. Metabolism and Endocrine Diseases

Reference

Ushiroyama T, Ikeda A, Higashino S, et al. Unkei-to for correcting luteal phase defects. *The Journal of Reproductive Medicine* 2003; 48: 729-34. CENTRAL ID: CN-00458287, Pubmed ID: 14562640

1. Objectives

To evaluate the efficacy of unkeito (温経湯) for luteal phase deficiency.

2. Design

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

3. Setting

Not mentioned (the authors belong to a clinic of the Department of Obstetrics and Gynecology, Osaka Medical College), Japan.

4. Participants

One-hundred and ninety-seven patients with a luteal phase of <10 days or a luteal-phase blood progesterone concentration of <10 ng/mL, who had not received hormone therapy for the past 12 months.

5. Intervention

Arm 1: oral administration of 2.5 g of TSUMURA Unkeito (温経湯) Extract Granules (TJ-106) t.i.d (daily dose 7.5 g), n=103.

Arm 2: untreated control group, n=94. (88 included for analysis)

(Note) During 2 to 8 days after ovulation, 5,000 IU of human chorionic gonadotropin (hCG) was injected three times in 71 of 103 patients in arm 1 and all 94 patients in arm 2.

6. Main outcome measures

Ovarian follicle size, endometrial thickness, and luteal function improvement rating (prolongation of luteal phase or elevation in progesterone value).

7. Main results

During days 14 to 18 of the menstrual cycle, most of the unkeito group showed significant improvement in both ovarian follicle size and endometrial thickness (83/103 patients in arm 1 vs. 13/88 patients in arm 2). Luteal functions were also significantly improved by unkeito treatment

8. Conclusions

Unkeito improves luteal phase defect.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned

11. Abstractor's comments

This paper is a follow-up of "Effects of unkeito, an herbal medicine, on endocrine function and ovulation in women with high basal level of luteinizing hormone secretion (*The Journal of Reproductive Medicine* 2001; 46: 451-6.) by Ushiroyama T, Ikeda A, Sakai M, et al." In addition to the previously reported efficacy of unkeito for ovulation disorder, the present paper reports its luteal phase-stabilizing effects including thickening of the endometrium and elevating progesterone value. Although the mechanism of action of unkeito remains unclear, this report provides further details of the effects of unkeito.

12. Abstractor and date

Nakata H, 1 April 2008.