## 4. Metabolism and Endocrine Diseases

### Reference

### 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 (溫経湯) 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.