

**14. Genitourinary Tract Disorders (including Climacteric Disorders)****Reference**

Sugimoto K, Shigehara K, Izumi K, et al. Effect of combination of saiko-ka-ryukotsu-borei-to with androgen replacement therapy for LOH syndrome. *Nihon Sei Kino Gakkai Zasshi (Japanese Journal of Sexual Medicine)* 2009; 24: 349–53 (in Japanese). Ichushi Web ID: 2010196632

**1. Objectives**

To evaluate the efficacy of androgen replacement therapy (ART) combined with saikokaryukotsuboreito (柴胡加竜骨牡蛎湯) for late-onset hypogonadism (LOH) syndrome.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

Two facilities (Kanazawa University Hospital and Ishikawa Prefectural Central Hospital), Japan.

**4. Participants**

Thirteen subjects who were diagnosed with LOH syndrome at the above facilities and desired to receive treatment.

**5. Intervention**

Arm 1: intramuscular testosterone enanthate 250 mg/3–4 weeks + administration of saikokaryukotsuboreito (柴胡加竜骨牡蛎湯) (manufacturer, not specified) 2.5 g t.i.d. immediately before meals for 12 weeks (n=6).

Arm 2: intramuscular testosterone enanthate 250 mg/3–4 weeks for 12 weeks (n=7).

**6. Main outcome measures**

1) Aging Males Symptoms (AMS) rating scale, 2) Self-rating Depression Scale (SDS), 3) self-rating Internal Index of Erectile Function-5 (IIEF-5), and 4) blood testosterone concentration, evaluated at the start of treatment and after 12 weeks of treatment.

**7. Main results**

Combination treatment tended to improve AMS, SDS, and IIEF-5 scores compared with ART alone. Decreases in blood total testosterone and free testosterone concentrations were greater after ART alone than after combination treatment.

**8. Conclusions**

Saikokaryukotsuboreito plus ART for late-onset hypogonadism (LOH) syndrome improves psychiatric and physical symptoms and alleviates ART-induced gonadal function depression.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Blood biochemistry identified no serious adverse events.

**11. Abstractor's comments**

This study focused on the central nervous system depressant activity of saikokaryukotsuboreito as a *saiko-zai* (柴胡劑, saiko formulation) or ryukotsu (竜骨)- and borei (牡蛎)-containing Kampo medicine, and compared the effect of its combination with androgen replacement therapy to that of androgen replacement therapy alone, using major rating scales clinically used to evaluate late-onset hypogonadism (LOH) syndrome. Its attempt to find out the favorable effects of Kampo medicine (when in combination) is worthy of appreciation. This study, however, fails to determine *sho* (証, pattern) of cases with appreciable depression and unidentified complaints, which are common in middle-aged and elderly men, and its finding that saikokaryukotsuboreito is more effective than ART alone for anxiety and depressive symptoms in cases of *ki-tai* (氣滯, qi stagnation) and *hi-ki-kyo* (脾氣虛, spleen qi deficiency) is consistent with conventional clinical wisdom and practice, and is not new. Furthermore, the sample size of 6–7 subjects per group was extremely small. It is hoped that similar studies will be performed with many more “saiko-*sho* (証, pattern)” and “ryukotsuborei- *sho* (証, pattern)” cases, which can be diagnosed by clinicians relatively early and without uncertainty to establish the guidelines for not only combination therapy with ART but also for selecting usage according to *sho* (証, pattern). Evaluation of whether a high percentage of patients with LOH syndrome is indicated for saikokaryukotsuboreito is also expected.

**12. Abstractor and date**

Ushiroyama T, 15 January 2011, 31 December 2013.