### **Evidence Reports of Kampo Treatment**

Task Force for Evidence Reports, the Japan Society for Oriental Medicine
Note) The quality of this RCT has not been validated by the EBM committee of the Japan Society for Oriental Medicine.

# 14. Genitourinary Tract Disorders (including Climacteric Disorders)

#### Reference

Koike K, Yamamoto Y, Suzuki N, et al. Efficacy of porcine placental extract on shoulder stiffness in climacteric women. *Climacteric* 2013; 16: 447-52. (in Japanese with English abstract) CENTRAL ID: CN-00920084, Pubmed ID: 23113540

#### 1. Objectives

To verify the clinical efficacy of porcine placental extract on shoulder stiffness in climacteric women.

### 2. Design

Randomized controlled trial (RCT).

# 3. Setting

Kanazawa University Hospital and Sugita Clinic (2 institutions), Japan.

# 4. Participants

Sixty-six climacteric women with shoulder stiffness.

### 5. Intervention

Arm 1: Three capsules/day of porcine placenta extract (350 mg/capsule) p.o. for 12 weeks, followed by 6 capsules/day p.o. for 12 weeks (n=33).

Arm 2: TSUMURA Tokishakuyakusan (当帰芍薬散) Extract Granules p.o. for 24 weeks (n=33).

### 6. Main outcome measures

Degree of shoulder stiffness on a visual analogue scale (VAS).

# 7. Main results

Among 66 patients enrolled, 7 patients did not complete the study. The VAS score was significantly lower (at the end of the study: 76.4% reduction from baseline, P<0.01) in arm 1 than in arm 2.

#### 8. Conclusions

Oral administration of porcine placenta extract is effective in improving prolonged shoulder stiffness in climacteric women.

# 9. From Kampo medicine perspective

None.

### 10. Safety assessment in the article

During the study period, administration of porcine placenta extract did not affect serum chemistry values, BMI, cardiovascular function, estradiol levels, or thyroid hormone levels, and did not cause abnormal uterine bleeding.

### 11. Abstractor's comments

Placenta extract is currently used as a supplement and advertised as a product effective in relieving menopausal symptoms. The present study evaluated the clinical efficacy of porcine placenta extract, focusing on shoulder stiffness in climacteric women. It deserves some appreciation. Placenta extract contains many bioactive substances, of which low molecular weight peptides, etc., are thought to enter the systemic circulation from the gastrointestinal tract and exert effects in target organs. Its mechanism of action, however, remains unknown. Prior treatment with tokishakuyakusan may also affect the results. It is hoped that the authors will also investigate the relationship and differences between biologics and Kampo.

### 12. Abstractor and date

Ushiroyama T, 6 June 2015, 5 October 2015.