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 climacteric symptoms in peri- and postmenopausal women. *Climacteric* 2013; 16: 28-35. Pubmed ID: 22920723

1. Objectives

To evaluate clinical effects of porcine placental extract on climacteric symptoms in peri-postmenopausal women.

2. Design

Randomized controlled trial (RCT).

3. Setting

One university hospital and 1 clinic, Japan.

4. Participants

Seventy-six women with climacteric symptoms.

5. Intervention

Arm 1: TSUMURA Tokishaykuyakusan (当帰芍薬散) Extract Granules administered orally at 7.5 g/day for 24 weeks (n=38).

Arm 2: Porcine placental extract (350 mg/capsule) administered orally 3 capsules/day for 12 weeks followed by 6 capsules/day for 12 weeks (n=38).

6. Main outcome measures

Severity (scores) of climacteric symptoms assessed by the simplified menopausal index (SMI), Zung self rating depression scale (ZSDS), and Spielberger state-trait anxiety inventory (STAI).

7. Main results

Compared with the tokishaykuyakusan alone group (control), the porcine placental extract group had significantly lower SMI and scores on the ZSDS and STAI (P<0.01).

8. Conclusions

Porcine placental extract may be an effective option for the treatment of climacteric symptoms in peri-postmenopausal women.

9. From Kampo medicine perspective None.

10. Safety assessment in the article

During the study period, porcine placental extract treatment did not affect other variables including serum chemistry levels and BMI and caused no adverse drug reactions.

11. Abstractor's comments

Placental extracts have been commercialized and used as a supplement to alleviate climacteric symptoms. This article is valuable because treatment effects of porcine placental extract on climacteric symptoms in peri-postmenopausal women were clinically evaluated using SMI, ZSDS score, and STAI score. Placental extract contains many bioactive substances, including low-molecular-weight peptides, which appear to be absorbed from the gastrointestinal tract into systemic circulation, where they affect targeted organs. However, their mechanisms are unknown. Although the influence of prior treatment with tokishaykuyakusan could not be ruled out, further studies on the relation and difference between these biopharmaceuticals and Kampo medicines are anticipated.

12. Abstractor and date

Ushiroyama T, 31 March 2017.