OBJECTIVE: To investigate the efficacy and safety of remifemin (isopropanolic extract of cimicifuga racemosa) treating perimenopausal symptoms in comparison of tibolone.

METHODS: One hundred and eighty postmenopausal women at range of 40 - 60 years old were enrolled in a multicenter, randomized and double blind study. They were divided into remifemin and tibolone group at ratio 1:1. The therapeutic strategy was remifemin 20 mg bid po for 12 weeks in remifemin group and tibolone 2.5 mg qd po for 12 weeks in tibolone group. To evaluate therapeutic effect, total score of Kupperman menopause index (KMI) was used as the major observed index and single item score of KMI were secondary observed index. Safety warning was determined by laboratory tests and adverse events at timepoint of before, at 4 and 12 weeks treatment.

RESULTS: (1) Total score of KMI: it were 24 +/- 5 in remifemin group and 25 +/- 6 in tibolone group before treatment. At timepoint of 4 weeks treatment, it were 11 +/- 6 in remifemin group and 11 +/- 7 in tibolone group. At timepoint of 12 weeks treatment, it were 7 +/- 6 in remifemin group and 6 +/- 5 in tibolone group. Total KMI score between two groups did not show statistical difference at various timepoint (P > 0.05). (2) Single item score of KMI: when compared before, at 4 and 12 weeks treatment, did show remarkable difference (P < 0.05) either in remifemin or in tibolone group. However, those single items of KMI score did not show statistical difference between 4 and 12 weeks timepoint in each treatment group (P > 0.05). (3) Adverse effect: the incidence of adverse effect in remifemin group was significantly lower than that of tibolone group. None case with vaginal bleeding was observed in remifemin group, however, 17 cases with vaginal bleeding occurred in tibolone group (19%, 17/90). The incidence of breast swelling were 16% (14/90) in remifemin group and 36% (32/90) in tibolone group; before treatment, the thickness of endometrium were (2.6 +/- 1.1) mm in remifemin group and (2.8 +/- 1.1) mm in tibolone group; at timepoint of 12 weeks treatment, the thickness of endometrium were (2.9 +/- 1.4) mm in remifemin group and (3.4 +/- 2.0) mm in tibolone group. In comparison of thickness of endometrium before and at 12 weeks treatment, no remarkable changes was observed in remifemin group, however, endometrium displayed significantly thicker in tibolone group.

CONCLUSIONS: Our study suggested that remifemin was one effective and safe agent to manage women with climacteric symptom. It has similar therapeutic effect and lower incidence of adverse effect when compared with tibolone.