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[Efficacy and safety of remifemin compared to tibolone for controlling of perimenopausal symptoms].

[Article in Chinese]

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Abstract

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**.

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Publication Types, MeSH Terms, Substances

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