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Efficacy and tolerability of a medicinal product containing an isopro

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Efficacy and tolerability of a medicinal product containing an isopropanolic black cohosh extract in Chinese women with menopausal symptoms: a randomized, double blind, parallel-controlled study versus tibolone.

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Abstract

OBJECTIVE: To investigate the efficacy-safety balance of the isopropanolic extract of *Actaea (=Cimicifuga) racemosa* (iCR, Remifemin) in comparison with tibolone in Chinese women with climacteric complaints.

METHOD: The randomized, double-blind, controlled 3-month study in 5 centers of 3 cities in China enrolled 244 menopausal patients aged 40-60 years and with a Kupperman Menopause Index (KMI) \geq 15. The participants were assigned to either iCR corresponding to 40 mg crude drug/day (N=122) or tibolone 2.5mg/day (N=122) orally. The primary endpoint was the combination of the Mann-Whitney values (MWV) of the KMI and the frequency of adverse events (benefit-risk balance) at end of treatment (MWV $>$ 0.5 shows superiority; MWV $>$ 0.36 shows non-inferiority).

RESULTS: KMI decreased from 24.7 \pm 6.1 to 11.2 \pm 6.2 and 7.7 \pm 5.8 (iCR) and to 11.2 \pm 7.2 and 7.5 \pm 6.8 (tibolone) at 4 and 12 weeks. This remarkable and clinically relevant improvement was similar in both treatment groups (MWV=0.47; 95% CI=0.39-0.54; p(non-inferiority)=0.002) showing statistical significant non-inferiority of iCR to tibolone. The KMI-responder rate was similar in both groups (84% and 85%). The safety evaluation showed for both groups a good safety and tolerability profile, however, there is a significant lower incidence of adverse events (p $<$ 0.0001) in favor of the herbal treatment. None of the postmenopausal iCR patients experienced vaginal bleeding in contrast to tibolone (17 cases). Breast and abdominal pain as well as leukorrhea was mostly observed in the tibolone group (p=0.015, p=0.008, p=0.002). No serious adverse event was observed in the iCR-group, however, two occurred in the tibolone-group. The benefit-risk balance for iCR was significantly (p=0.01) superior to tibolone (MWV=0.56; 95% confidence interval [0.51-0.62]).

CONCLUSION: The efficacy of iCR (medicinal product Remifemin) is as good as tibolone for the treatment of climacteric complaints, even for moderate to severe symptoms, whereby iCR is clearly superior regarding the safety profile. This iCR containing medicinal product is an excellent option for treatment of climacteric complaints which has now for the first time been verified in Asian women.