



NON-HORMONAL TREATMENT OF CLIMACTERIC COMPLAINTS WITH ISOPROPANOLIC CIMICIFUGA RACEMOSA EXTRACT ICR - AN OVERVIEW OF CLINICAL DATA

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Context & Objective: While efficacy data for Cimicifuga racemosa (CR) food supplements is regarded as insufficient, the European Medicines Agency clearly approved a positive benefit-risk-ratio for Cimicifuga racemosa (CR) medicinal products (MP). The best documented and most thoroughly investigated CR MP is the isopropanolic CR extract (iCR). Here we give an overview of the clinical data generated with iCR extract after the EU GCP Guideline E6 came into effect.

Methods: Publications from 1997-2017 (e. g. from MEDLINE, EMBASE, BIOSIS, EMBASE Alert) were collected and analysed for iCR's efficacy and safety in patients with climacteric symptoms.

Patients, Interventions & Main Outcome Measures: A total of 42,631 patients, of which 12,876 were treated with iCR extract, were included in 31 clinical studies. Efficacy (e. g. menopausal symptom scales, quality of life, polysomnography) and safety (tolerability, safety at estrogen-sensitive tissue and liver) of iCR treatment were analysed.

Results: The clinical studies, among them 12 randomized controlled trials (RCT) and 1 meta-analysis, consistently demonstrate iCR's efficacy and safety. Neurovegetative and psychic symptoms, including insomnia, are significantly reduced compared to placebo. Efficacy is equal to low-dose transdermal hormone therapy or tibolone. Yet, compared to tibolone iCR shows a better safety profile. High-dosed iCR combined with St. John's wort also demonstrates its efficacy vs. placebo and ameliorates psychic complaints better than iCR monotherapy - thus extending therapeutic options for patients with more severe or pronounced psychic climacteric complaints. iCR is well tolerated and does not affect estrogen-sensitive tissue. No evidence for hepatotoxicity could be found in clinical trials. Breast cancer survivors using iCR have a reduced risk for tumour recurrence. A large case-control study suggests breast cancer protective effects for iCR.

Conclusions: iCR extract is effective and safe in ameliorating vasomotor, psychic and sleep complaints of climacteric patients. As a monograph-compliant MP with consistent Level 1-Evidence, iCR extract can be recommended for women who do not want to or cannot treat their climacteric symptoms with hormone therapy.

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