

- **The Cimicifuga preparation BNO 1055 vs. conjugated estrogens in a double-blind placebo-controlled study: effects on menopause symptoms and bone markers.**

Wuttke W, Seidlova-Wuttke D, Gorkow C.

Department of Clinical and Experimental Endocrinology, University of
Gottingen, Robert-Koch-Strasse 40, 37075 Gottingen, Germany.
ufkendo@med.uni-goettingen.de

OBJECTIVES: In the present study, therapeutic effects of the Cimicifuga racemosa preparation CR BNO 1055 (Klimadynon/Menofem) on climacteric complaints, bone metabolism and endometrium will be compared with those of conjugated estrogens (CE) and placebo. The question whether CR BNO 1055 contains substances with selective estrogen receptor modulator (SERM) activity will be investigated. **METHODS:** Sixty-two evaluable postmenopausal women were included in the double-blind, randomized, multicentre study, and treated either with CR BNO 1055 (daily dose corresponding to 40 mg herbal drug), 0.6 mg CE, or matching placebo, for 3 months. Menopausal symptoms were assessed by the menopause rating scale (MRS) and a diary. Levels of CrossLaps (marker of bone degradation) were determined by ELECSYS system and bone-specific alkaline phosphatase (marker of bone formation) by an enzymatic assay. Endometrial thickness was measured via transvaginal ultrasound; vaginal cytology was also studied. The primary efficacy criterion was the change from baseline to end point in the MRS. Change from baseline was analyzed for the secondary variables too. **RESULTS:** CR BNO 1055 proved to be equipotent to CE and superior to placebo in reducing climacteric complaints. Under both verum preparations, beneficial effects on bone metabolism have been observed in the serum. CR BNO 1055 had no effect on endometrial thickness, which was significantly increased by CE. Vaginal superficial cells were increased under CE and CR BNO 1055 treatment. **CONCLUSION:** The results concerning climacteric complaints and on bone metabolism indicate an equipotent effect of CR BNO 1055 in comparison to 0.6 mg CE per day. It is proposed that CR BNO 1055 contains substances with SERM activity, i.e. with desired effects in the brain/hypothalamus, in the bone and in the vagina, but without exerting uterotrophic effects.