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## An isopropanolic extract of black cohosh does not increase mammographic breast density or breast cell proliferation in postmenopausal women.

Hirschberg AL<sup>1</sup>, Edlund M, Svane G, Azavedo E, Skoog L, von Schoultz B.

### Author information

### Abstract

**OBJECTIVE:** The aim of this study was to determine the effects of the **isopropanolic extract of black cohosh** (Remifemin) on mammographic **breast** density and **breast** epithelial **proliferation** in healthy, naturally **postmenopausal women** with climacteric symptoms.

**DESIGN:** This was a prospective, open, uncontrolled drug safety study in which baseline status was compared with status after 6 months of treatment by blinded observers. A total of 74 **women** were treated with 40 mg **black cohosh** daily, and 65 **women** completed the study.

Mammograms were performed, and **breast** cells were collected by percutaneous fine needle aspiration biopsies at baseline and after 6 months. Mammographic density was quantified according to the Wolfe classification or a percentage scale. **Breast cell proliferation** was assessed using the Ki-67/MIB-1 monoclonal antibody. Safety was monitored by adverse event reporting, laboratory assessments, and measurement of the endometrium by vaginal ultrasound.

**RESULTS:** None of the **women** showed any increase in mammographic **breast** density. Furthermore, there was no increase in **breast cell proliferation**. The mean change +/- SD in proportion of Ki-67-positive cells was -0.5% +/- 2.4% (median, 0.0; 95% CI = -1.32 to 0.34) for paired samples. The mean change in endometrial thickness +/- SD was 0.0 +/- 0.9 mm (median, 0.0). A modest number of adverse events were possibly related to treatment, but none of these were serious. Laboratory findings and vital signs were normal.

**CONCLUSIONS:** The findings suggest that the **isopropanolic extract of black cohosh** does not cause adverse effects on **breast** tissue. Furthermore, our data do not indicate to any endometrial or general safety concerns during 6 months of treatment.

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