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Efficacy of Vitex agnus castus L. extract Ze 440 in patients with pre-menstrual syndrome (PMS).

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In a prospective, multicentre trial the efficacy of an Vitex agnus castus L extract Ze 440 was investigated in 50 patients with pre-menstrual syndrome (PMS). The patients were treated daily with one tablet (20 mg native extract) during three menstrual cycles. 43 patients completed the study protocol which encompassed 8 menstrual cycles (2 baseline, 3 treatment and 3 post-treatment). 13/43 patients were receiving concomitant oral contraceptives. 6 patients did not complete the study for reasons not related to study medication, and one patient complained of fatigue possibly related to study medication. All evaluated patients took at least 85% of the prescribed medication. The main effect parameter was the validated Moos' menstrual distress questionnaire (MMDQ), and secondary parameters were a visual analogue scale (VAS; self-assessment) and a global impression scale (GI, self-assessment). The study population was homogenous in age (31.3+/-7.7 years) weight (58.9+/-6.9 kg) and cycle length (28.4+/-0.3 d). The diagnosis was according to DMS-III. At the end of the study, PMS-related symptoms were reduced by treatment. There was a significant score reduction (42.5%) of the MMDQ as the main effect parameter ($p<0.001$). Symptoms gradually returned after treatment cessation. However, a difference from baseline remained (20%; $p<0.001$) up to 3 cycles thereafter. 20/43 patients were considered "responders", with a reduction in MMDQ score by at least 50% relative to baseline. At baseline, the VAS score was elevated in the late luteal phase and low at the follicular phase, as expected. During treatment, VAS score decreased in the late luteal phase (47.2%; $p<0.01$) and remained 21.7% ($p<0.001$) below baseline after 3 cycles post-cessation of treatment. The low VAS score within the follicular phase remained unchanged over the whole observation period. 38 patients judged the global efficacy moderate to excellent, 5 patients indicated no global efficacy. The number of days patients sustained PMS symptoms was reduced slightly from 7.5 to 6. Resting levels of blood prolactin remained within the physiological range throughout. No differences were seen between patients on or off oral contraceptives. 20 patients reported 37 adverse events (AE). No serious AE were reported. One patint withdrew after four days of treatment due to fatigue and headache. Laboratory safety control parameters were not affected. In conclusion, patients with PMS can be treated successfully with Vitex agnus-castus extract Ze 440, as indicated by clear improvement in the main effect parameter during treatment and the gradual return after cessation of treatment. The main response to treatment seems related to symptomatic relief rather than to the duration of the syndrome.

Publication Types:

- Clinical Trial
- Multicenter Study

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