A multicentre open clinical trial to assess the tolerability and efficacy of Sage tablets in climacteric women with hot flushes

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Introduction
Sage has been traditionally used as a tonic, against mental and physical exhaustion, hyperhidrosis, and hot flushes in menopause. Whilst most women suffer from menopausal symptoms during the climacteric period, many are reluctant to rely on HRT (1) and inclined to resort to phytotherapeutic treatments.

A new Sage fresh plant extract in once daily application demonstrated good clinical tolerability and efficacy in a once daily application of a dosage corresponding to the monographs of ESCOP (2) and Commission E (3) in an open clinical trial in menopausal women with hot flushes.

Methods

Demographic data
We included 69 women (mean age 56 years) with hot flushes

Efficacy
• Statistically significant decrease of the TSIRH score (total score of the mean number of intensity-rated hot flushes) after 8 weeks (p < 0.0001), reduction of 50% already after 4 weeks of therapy (p = 0.0001) and by 50% after 4 weeks (p = 0.0001). Reduction of:
  • Mild flushes from 3.7±2.4 to 0.5±0.5 (p < 0.0001)
  • Moderate flushes from 3.9±4.6 to 1.5±2.8 (p < 0.0001)
  • Severe flushes from 3.4±4.3 to 0.3±0.3 (p = 0.0001)
  • Very severe flushes from 0.3±1.2 to 0.0±0.2 (p = 0.0001)
• Statistically significant decrease of the score of the MRS and all subscales:
  • Menopausal subscore (by about 6.6±9.9 score points from 14.5 to 6.6 (p < 0.0001)
  • Somato-vegetative subscale by about 3.3±4.8 score points from 7.6 to 4.3 (p < 0.0001)
  • Psychological subscale by about 2.7±5.5 score points from 5.8 to 3.1 (p < 0.0001)
  • Urogenital subscale by about 0.3±1.1 score points from 1.5 to 1.2 (p = 0.01)
• Significant decrease (p < 0.05) each week compared to previous week (except for weeks 4/5 and 6/7)

Safety
Adverse events
• 10 adverse events occurring in 6 patients were reported, of these only two (abdominal pain and diarrhea, both of mild intensity) were judged to be related to the study medication.
• Tolerability was rated as very good or good by 90% of physicians and patients.

Laboratory assessments
The evaluation of the laboratory parameters demonstrated a high degree of safety. No significant changes in the mean of (trans)aminase enzymes, hematocrit, hemoglobin, INR, MCV, MCH, MCHC, ESR, or thrombocyte sedimentation rates, or thrombocyte counts, sodium, potassium, calcium, creatinine, jaundice and cholesterol were observed.