Salvia Extract for the Treatment of Menopausal Symptoms: A Randomized, Controlled, Double-Blind Clinical Trial

Silvia Bommer | Gwladys Nina Dipah | Andy Suter | Roland Schoop | Wilfried Dimpfel

1 A. Vogel AG, 9325 Roggwil, Switzerland
2 NeuroCode AG, 35578 Wetzlar, Germany
3 Justus-Liebig-University Giessen c/o NeuroCode AG, 35578 Wetzlar, Germany

Conclusion

Four weeks of Salvia officinalis (Menosan® Salvia) treatment significantly alleviated a broad complex of menopausal symptoms with a high specificity for hot flushes. It induced a higher mental capacity and a more relaxed state of mind compared to placebo. EGG data documented an impact on central nervous transmitter systems involved in neuroadaptive processes as required by the physiological estrogen decline in menopause.

Introduction

Menopausal transition is typically accompanied not only by hot flushes but also by mood alterations and sleep disorders, rooted in dysregulation of central nervous transmitter activities. Salvia officinalis has been traditionally applied to treat these symptoms. This study examined in a randomized placebo controlled, double-blind clinical setting the correlation of the clinical findings to brain waves' activity associated with central nervous transmitter systems.

Patients and Methods

Inclusion criteria

Age 48 – 65 years (both including), menopausal since ≥ 1 year, positive HFS ≥ 10, BMI between 18.0 and 35.0, ≥ 5 hot flushes / 24 h or daily intense hot flushes, disturbing sweating (Visual Analogue Scale 8-10), unobtrusive case history and findings, negative alcohol and drug-test, negative pregnancy test.

Investigated parameters

Efficacy

The primary clinical endpoints menopausal rating scale [MRS] and hot flush severity and incidence [HFS] were monitored throughout therapy and correlated with quantitative electroencephalographic [qEEG] measurements in a per protocol analysis.

Safety

Patients underwent before and at the end of study a clinical exam (bp, bp and temperature) and a safety lab testing (blood count, Na+, GOT, GPT, GGT, creatinine, glucose and urine status and sediment).

Treatment regimen

Daily one tablet of Menosan® Salvia [3’400 mg ethanolic extract of Salvia officinalis] or placebo under randomized double-blind conditions for 4 weeks.

Results

Eighty menopausal women between 48 – 65 years of age (average: 56±4 years) were screened, recruited and randomly assigned to Salvia off. and placebo group.

Safety

Tolerability of both treatment regimens, i.e. Salvia off. and placebo, were rated by patients and physicians alike in 100% of cases as very good. A total of 3 adverse events, all unrelated to the study medication were recorded: a car accident (n = 1), herpes zoster (n = 1) and for placebo: lumbago (n = 1).

For placebo and Salvia off. group there were no relevant or related changes in vital signs and laboratory safety parameters recorded.

Efficacy

Salvia officinalis (Menosan® Salvia) potently reduced the MRS sum score by 39.2% from 15.3 ± 6.87 to 9.3 ± 5.75 and significantly in comparison to placebo (p=0.002). The somato-vegetative subscale improved by 40.8% from 15.3 ± 6.87 to 9.3 ± 5.75 and significantly in comparison to placebo (p=0.002). The somato-vegetative subscale improved by 40.8% from 15.3 ± 6.87 to 9.3 ± 5.75 and significantly in comparison to placebo (p=0.002). The somato-vegetative subscale improved by 40.8% from 15.3 ± 6.87 to 9.3 ± 5.75 and significantly in comparison to placebo (p=0.002). The somato-vegetative subscale improved by 40.8% from 15.3 ± 6.87 to 9.3 ± 5.75 and significantly in comparison to placebo (p=0.002). The somato-vegetative subscale improved by 40.8% from 15.3 ± 6.87 to 9.3 ± 5.75 and significantly in comparison to placebo (p=0.002). The somato-vegetative subscale improved by 40.8% from 15.3 ± 6.87 to 9.3 ± 5.75 and significantly in comparison to placebo (p=0.002). The somato-vegetative subscale improved by 40.8% from 15.3 ± 6.87 to 9.3 ± 5.75 and significantly in comparison to placebo (p=0.002). The somato-vegetative subscale improved by 40.8% from 15.3 ± 6.87 to 9.3 ± 5.75 and significantly in comparison to placebo (p=0.002). The somato-vegetative subscale improved by 40.8% from 15.3 ± 6.87 to 9.3 ± 5.75 and significantly in comparison to placebo (p=0.002).

Sleep quality as per questionnaire (SF-B/R) and fatigue in profile of mood states (POMS) significantly improved with Salvia off., whilst the HAMA showed a non-significant trend only. Clinical effects for Salvia off. treatment found a pharmacological correlation in changes of alpha1, alpha 2, delta, theta, beta1 and beta2 qEEG values.

Contact address:
Silvia Bommer, Bioforce AG, CH – 9325 Roggwil
Email: s.bommer@bioforce.ch

Figure 1: Change of hot flush severity score during four weeks treatment with Salvia off.

Figure 2: Change of MRS score from Day 0 to Day 28 under treatment with Salvia off.

Figure 3: Percentage of patients with ≥50 % reduction rate of the global Menopause Rating Scale (Sum score) and MRS subscales after 28 days of treatment with Salvia off.

Figure 4: Change of mean activity of distinct frequency ranges (delta, theta, alpha1 and alpha2, beta1 and beta2) on Day 28 (after 4 weeks’ therapy) compared to baseline Day 0 (not in 100% under qEEG recording conditions).

Figure 5: Sleep quality per questionnaire (SF-B/R) and fatigue in profile of mood states (POMS) significantly improved with Salvia off., whilst the HAMA showed a non-significant trend only. Clinical effects for Salvia off. treatment found a pharmacological correlation in changes of alpha1, alpha 2, delta, theta, beta1 and beta2 qEEG values.