

Symposium Poster

Randomized Placebo-controlled Double-blind Clinical Trial of a Special Extract of Kava Roots (WS 1490) in Patients with Anxiety Disorders of Non-psychotic Origin

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The efficacy and safety of a special extract (WS 1490) of kava roots (rhizoma piperis methystici) were investigated in a randomized, double-blind, placebo-controlled, single-centre trial in patients with anxiety disorders of non-psychotic origin after previous treatment with a benzodiazepine preparation.

A total of 40 patients were included in the trial and were treated with the test preparation for 36 days. During the first eight days of treatment the dosage of the test drug was gradually increased from 50 mg to 300 mg daily, whereas the benzodiazepine treatment was reduced and then stopped within two weeks. After a single three weeks treatment period with test preparation or placebo the patients were observed in a follow-up period of another three weeks.

The primary outcome variables were the change in the total score of the Hamilton Rating Scale for Anxiety (HAMA), the change in the total score of a wellbeing-scale (Bf-S according to von Zerssen) and the frequency of withdrawal symptoms during the treatment phase with WS 1490 or placebo, which

were evaluated for 39 patients (WS 1490: 20, placebo: 19). There was a significant superiority of WS 1490 over placebo with respect to the change of the HAMA score ($p = 0.01$), to the change of the Bf-S score ($p = 0.01$) and an advantage regarding the frequency of withdrawal symptoms.

The WS 1490 was also superior to placebo with respect to the HAMA subscores for somatic symptoms and psychic symptoms as well as the scores of the Erlangen-Anxiety-Tension-Aggressivity-Scale (EAAS according to Lehrl) and the Clinical Global Impressions, items 1 to 3, ($p < 0.05$ each) at the end of the treatment phase. After discontinuation of the treatment patients who had been under WS 1490 therapy exhibited significantly more recurrences than patients who had been under placebo ($p < 0.05$).

WS 1490 was found to be very well tolerated. There was a total of 18 adverse events (WS 1490: 6, placebo: 12), with all adverse events being assessed as withdrawal symptoms. The trial confirms the clinical efficacy of WS 1490 in the treatment of patients suffering from anxiety disorders of non-psychotic origin and that it is very well tolerated.