Efficacy and safety of crataegus extract WS 1442 in comparison with placebo in patients with chronic stable New York Heart Association class-III heart failure.

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OBJECTIVE: The purpose of this study was to investigate whether long-term therapy with crataegus extract WS 1442 is efficacious as add-on therapy to pre-existing diuretic treatment in patients with heart failure with a more advanced stage of the disease (New York Heart Association [NYHA] class III), whether effects are dose dependent, and whether the treatment is safe and well tolerated.

METHODS: Exercise capacity was assessed by use of seated bicycle ergometry with incremental workloads. Scores for subjective symptoms and complaints made by the patients were analyzed. Efficacy and tolerability of the treatments were judged by both the patients and investigators. Safety was assessed by the documentation of adverse events and the safety laboratory.

RESULTS: A total of 209 patients were randomized to treatment with 1800 mg of WS 1442, 900 mg of WS 1442, or with placebo. After 16 weeks of therapy with 1800 mg of WS 1442 per day, maximal tolerated workload during bicycle exercise showed a statistically significant increase in comparison with both placebo and 900 mg of WS 1442. Typical heart failure symptoms as rated by the patients were reduced to a greater extent by WS 1442 than by placebo. This difference was significant for both doses of WS 1442. Both efficacy and tolerability were rated best for the 1800 mg of WS 1442 group by patients and investigators alike. The incidence of adverse events was lowest in the 1800 mg of WS 1442 group, particularly with respect to dizziness and vertigo.

CONCLUSIONS: The data from this study confirm that there is a dose-dependent effect of WS 1442 on the exercise capacity of patients with heart failure and on typical heart failure-related clinical signs and symptoms. The drug was shown to be well tolerated and safe.