

Rhodiola rosea in Subjects with Prolonged or Chronic Fatigue Symptoms: Results of an Open-Label Clinical Trial.

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Abstract

BACKGROUND: Rhodiola rosea roots and rhizomes are a herbal medicine for temporary relief of stress symptoms such as fatigue and sensed weakness. A daily dosage of 400 mg is recommended.

METHODS: A dry ethanolic extract of *R. rosea* (WS® 1375) was studied in 100 subjects with prolonged or chronic fatigue symptoms. In an uncontrolled, open-label multicenter clinical trial, the subjects were administered 2 × 200 mg WS® 1375 over 8 weeks. Outcome measures were scales and tests related to fatigue. They were evaluated in an exploratory data analysis to generate hypotheses regarding efficacy. The pilot character of the trial is marked by its broad focus on subjects suffering from fatigue in general and by its comparatively long duration.

RESULTS: The greatest change was observed after 1 week of treatment. The fatigue symptoms continued to decline further, with statistically significant improvement at week 8. The safety assessments of WS® 1375 during the trial proved to be favorable, with most adverse events being of mild intensity and not related to the study drug.

CONCLUSIONS: The results indicate that 2 × 200 mg WS® 1375 may be an effective treatment in subjects suffering from prolonged or chronic fatigue. The safety and tolerability of WS® 1375 also presented a favorable profile.

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