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HerbClip™

FILE: ▪Rhodiola (*Rhodiola rosea*)
▪SHR-5®
▪Depression

HC 110677-342

Date: December 14, 2007

RE: Special Swedish Rhodiola Extract Shows Benefit in Mild to Moderate Depression in Clinical Trial

Darbinyan V, Aslanyan G, Amroyan E, Gabrielyan E, Malmström C, Panossian A. Clinical trial of *Rhodiola rosea* L. extract SHR-5 in the treatment of mild to moderate depression. *Nord J Psyc.* 2007;61:343-348.

Rhodiola (*Rhodiola rosea*) is a medicinal plant with adaptogenic, antioxidant, endocrine, reproductive, and central nervous system effects.[1] Rhodiola root preparations have been extensively studied and used in Scandinavia and Russia as an herbal medicine.[1]

In this double-blind, placebo-controlled, randomized phase III clinical trial, the authors examine the effect of the proprietary standardized rhodiola rhizome extract SHR-5 on mild to moderate depression. Both SHR-5 and the placebo were manufactured by the Swedish Herbal Institute (Gothenburg, Sweden) following Good Manufacturing Practices. (SHR-5 is used in the special extract Arctic Root® and is available in the United States from ProActive BioProducts, Inc., Phoenix, AZ). Each 400 mg tablet of SHR-5 contained 170 mg of rhodiola extract. SHR-5 is a standardized extract of rhodiola root that provides 4.5 mg of salidroside in 185 mg of extract. The placebo contained 170 mg lactose. The study medication and the placebo were virtually identical in appearance.

Male and female patients aged 18-70 years (n=89) and diagnosed with mild to moderate depression according to the DSM-IV[2] were recruited from the clinics of Erebouni Medical Center (Armenian State Medical University, Yerevan, Armenia). There is no indication if these patients were inpatients or outpatients. During a 2-week run-in period, the patients received no medication. Then, patients were randomized to receive 2 tablets once daily of SHR-5 (340 mg/day) (n=31), 2 tablets twice daily of SHR-5 (680 mg/day) (n=29), or 2 placebo tablets once daily (n=29). The randomization method used followed the "principles of total randomization, whereby each patient was randomly assigned an integer 1-90."

The Beck Depression Inventory (BDI) and the Hamilton Rating Scale for Depression (HAMD) were applied to the patients on Day 0 and Day 42 of the 6 week study period. Two patients dropped out of the trial "for non-medical reasons." No adverse effects were reported. After 6 weeks, the HAMD scores showed that symptoms were significantly improved for the 2 groups receiving SHR-5 ($P<0.0001$). For the low-dose SHR-5 group (340 mg/day), the average total HAMD score decreased from 24.52 to 15.97 ($P<0.0001$). The average total HAMD score decreased from 23.79 to 16.72 ($P<0.0001$) for the high-dose SHR-5 group (680 mg/day). The average total HAMD scores of the 2 SHR-5 groups were significantly different from the placebo group at the end of the study ($P<0.001$). The placebo group did not show a significant improvement in HAMD scores. In addition, the HAMD ratings for self-esteem were significantly improved in the high-dose SHR-5 group ($P=0.0002$).

This clinical trial shows that the special rhodiola rhizome extract SHR-5 "possesses a clear and significant anti-depressive activity in patients suffering from mild to moderate depression." In addition, the extract appears to be safe for short-term use, with no adverse effects reported. The authors expect that future clinical trials including a 12-week follow-up period and a larger multi-center study design will show how the efficacy of SHR-5 compares with conventional pharmaceutical antidepressants. In addition, more research is needed to confirm the mechanism of action for this observed antidepressant activity.

Dr. Richard P. Brown, MD, Associate Professor of Clinical Psychiatry at the Columbia University College of Physicians and Surgeons, states "In addition to mood elevation, evidence indicates that *R. rosea* has numerous other benefits, including enhancement of cognitive function, sexual function, and both mental and physical performance under stress. Additional studies are needed to explore and establish the potential applications of this herbal extract. In the meantime, phytomedicinal researchers and consumers can be encouraged by these findings." (personal communication to Mark Blumenthal, November 19, 2007)

—Marissa Oppel, MS

References

1. Brown R, Gerbarg P, Ramazanov Z. Rhodiola rosea - a phytomedicinal overview. *HerbalGram*. 2002;56:40-52.
2.*Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)*. Washington, DC: American Psychiatric Association; 1994.

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