

Esketamine safe, effective for treatment-resistant depression

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(HealthDay)—Esketamine seems to be efficacious and safe for patients

with treatment-resistant depression (TRD), according to a study published online Dec. 27 in *JAMA Psychiatry*.

Ella J. Daley, M.D., from Janssen Research & Development LLC in Titusville, N.J., and colleagues conducted a phase 2, double-blind, doubly randomized, delayed-start, placebo-controlled study to examine the efficacy, safety, and dose-response of intranasal esketamine hydrochloride. A total of 67 adults with a diagnosis of [major depressive disorder](#) and history of inadequate response to two or more antidepressants (TRD) were randomized and 60 completed two one-week double-blind treatment periods. In period 1, participants were randomized to placebo or esketamine 28, 56, or 84 mg twice weekly (33, 11, 11, and 12 participants, respectively). In period 2, 28 placebo-treated participants were re-randomized to one of the four treatment arms.

The researchers found that the change in Montgomery-Åsberg Depression Rating Scale total score was superior in all three esketamine groups versus placebo (least squares mean difference versus placebo: esketamine 28 mg: -4.2; 56 mg: -6.3; 84 mg: -9.0), with a significant ascending dose-response relationship. Despite reduced dosing frequency in the open-label phase, the improvement in depressive symptoms appeared to be sustained (-7.2).

"In this first clinical study to date of intranasal esketamine for TRD, antidepressant effect was rapid in onset and dose-related," the authors write. "Results support further investigation in larger trials."

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