



WHAT DO THESE RESULTS MEAN FOR INDIVIDUALS WITH TREATMENT-RESISTANT DEPRESSION?

Esketamine nasal spray monotherapy was associated with clinically meaningful reductions in depressive symptoms in adults with treatment-resistant depression. Higher rates of response and remission were observed with esketamine compared with placebo, and these effects were generally consistent across subgroups defined by baseline depression severity and number of prior unsuccessful antidepressant treatments.



WHAT WAS THE PURPOSE OF THIS STUDY?

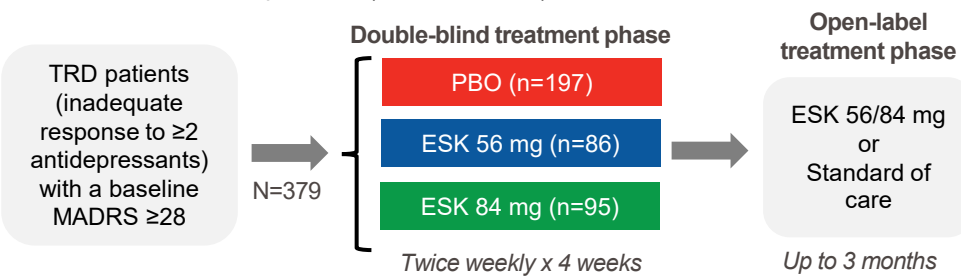
- The purpose of this study is to evaluate the efficacy and safety of esketamine nasal spray used alone (monotherapy) in adults with treatment-resistant depression (TRD), by baseline depression severity and number of prior unsuccessful antidepressants (ADs).



WHO WAS IN THE STUDY AND HOW WAS IT CARRIED OUT?

Figure 1: Study Design and Patient Characteristics

A post-hoc analysis was conducted for a phase 4, randomized, double-blind clinical trial that studied esketamine nasal spray used alone (monotherapy) in adults with treatment-resistant depression (NCT04599855).



MADRS, Montgomery-Asberg Depression Rating Scale; ESK, esketamine; PBO, placebo

Key Outcomes:

Change in depression (MADRS) scores from baseline to day 28

Side effects reported during the study

Baseline Characteristics

2 previous unsuccessful antidepressants

59.3%

Patient characteristics were similar across treatment groups

Median baseline MADRS total score

37.0
(severe)

Baseline MADRS total score ≤37

52.6%

Normal 0-6

Mild 7-19

Moderate 20-34

Severe 35-60

Efficacy of Esketamine Nasal Spray Monotherapy for Treatment-Resistant Depression: Post Hoc Analysis by Baseline Disease Severity and Prior Treatment

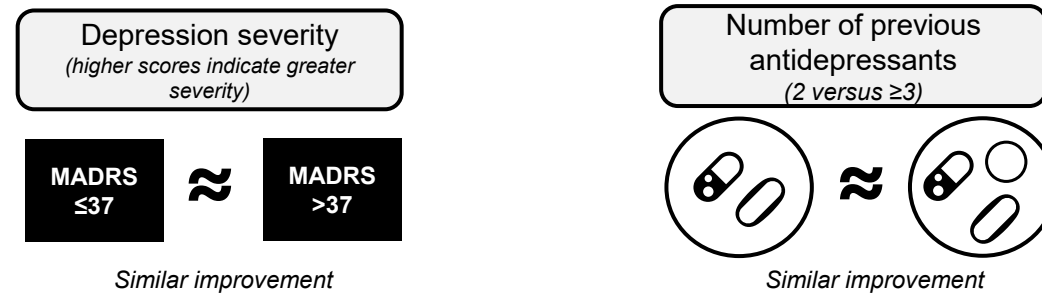
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WHAT WERE THE RESULTS?

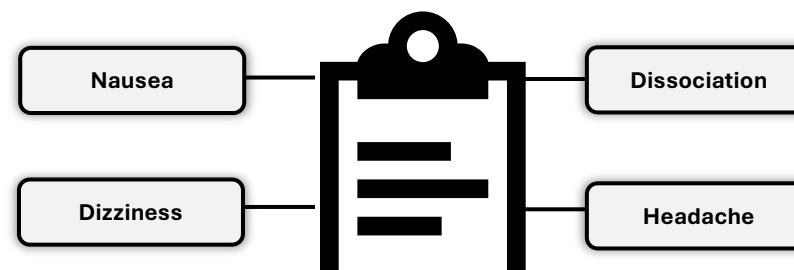
Figure 2: How did starting depression severity and prior treatments affect improvement?



More patients treated with esketamine nasal spray achieved response (≥50% improvement in MADRS score) and remission (MADRS score ≤12) compared with placebo, regardless of starting depression severity or prior unsuccessful antidepressant treatments.

Figure 4: Most common side effects

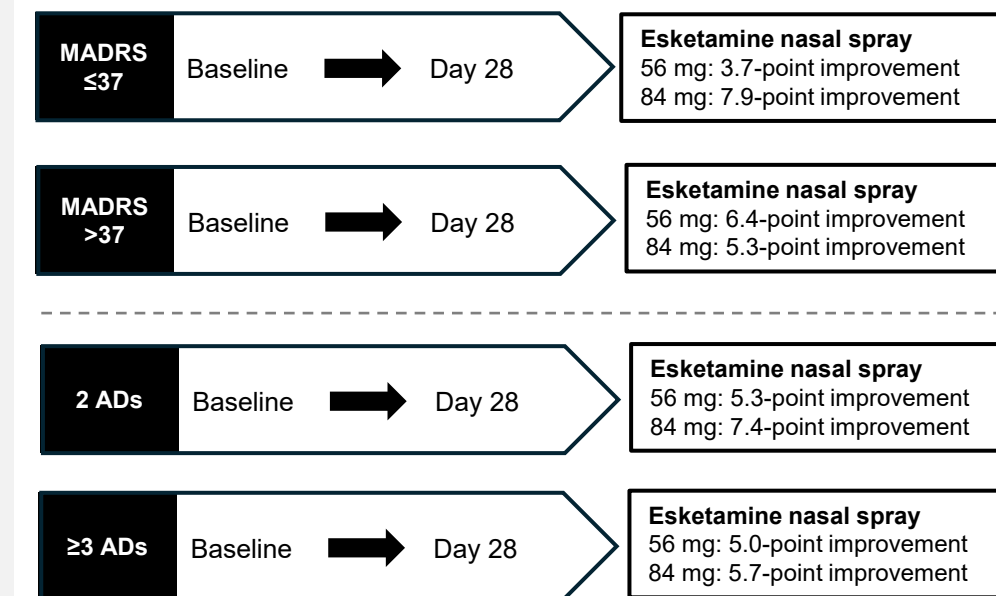
Most common side effects reported in ≥10% of patients treated with esketamine



These side effects were reported more frequently in the esketamine groups than placebo and were generally consistent with the known safety profile of esketamine nasal spray.

Figure 3: How did depression scores change from baseline to day 28?

Differences in total MADRS from baseline to day 28 compared to PBO



WHAT WERE THE LIMITATIONS OF THIS STUDY?

This was a post hoc analysis, meaning it was conducted after the study was completed and the outcomes assessed were not planned in the original study design; therefore, the findings are exploratory and should be interpreted with caution. The study also had a short treatment duration (28 days), limiting conclusions about long-term effects.

Glossary of Terms

Baseline	The starting point of the study, before any treatment was given, used to compare changes over time.	Esketamine	A prescription medication given as a nasal spray that is used to treat adults with treatment-resistant depression.	MADRS	Montgomery-Asberg Depression Rating Scale, a tool used by clinicians to measure severity of depression symptoms. Higher scores indicate more severe depression.
Response	A meaningful improvement in depression symptoms, defined in this study as at least a 50% reduction in the MADRS score from baseline.	Remission	A state where depression symptoms are greatly reduced, defined in this study as a MADRS score of 12 or lower.	Dissociation	A temporary feeling of being disconnected from yourself or your surroundings. Some people may feel "spaced out," detached, or as if things around them do not feel quite real.



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