

Plain Language Summary

Rapid and Sustained Remission with Esketamine Nasal Spray in Adult Patients with Treatment-Resistant Depression: Overview of Remission Rates from Six Clinical Trials



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What do these results mean for individuals with treatment-resistant depression (TRD)?

Rapid and sustained remission is achievable in adults with TRD on esketamine, supporting its role as a treatment option in clinical practice.

Purpose of the analysis

To summarize remission rates (defined as MADRS total score ≤ 10) across six TRD clinical trials in patients who received esketamine consistent with US prescribing information.



- **Treatment-resistant depression:** Major depressive disorder that has not adequately responded to at least two antidepressants.
- **Esketamine:** A nasal spray approved for treatment-resistant depression in adults.
- **Montgomery-Åsberg Depression Rating Scale (MADRS):** Clinician rated scale measuring depression severity, scores range 0-60.
- **Remission:** MADRS total score ≤ 10 , indicative of near or complete resolution of depressive symptoms

How was the analysis conducted and what was the design?

Data from six TRD trials were analyzed. Baseline demographics, disease factors, efficacy, and safety data of patients from each study are summarized descriptively.

Data was collected from **6 esketamine clinical trials for TRD:**

4-week placebo-controlled trials

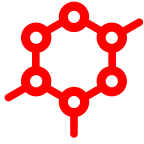
- **TRD4005:** phase 4, double-blind, randomized, monotherapy trial of esketamine 56 mg or 84 mg vs placebo nasal spray
- **TRANSFORM-2:** phase 3, double-blind, randomized trial of esketamine 56 mg or 84 mg plus an oral antidepressant vs placebo nasal spray plus an oral antidepressant

Active-controlled trial

- **ESCAPE-TRD:** phase 3b, open-label, single-blind trial of esketamine + selective serotonin reuptake inhibitor (SSRI)/serotonin and norepinephrine reuptake inhibitor (SNRI) vs quetiapine extended release + SSRI/SNRI

Open-label trials

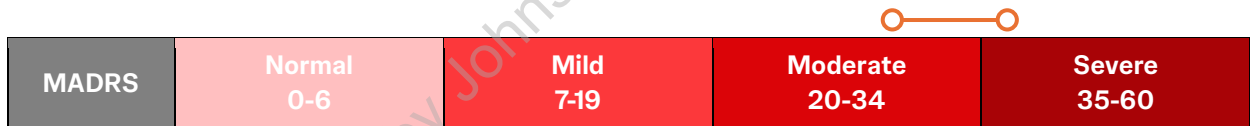
- **ESCAPE long-term extension:** phase 4, single-arm, open-label trial of esketamine + SSRI/SNRI
- **SUSTAIN-2:** phase 3, open-label trial of esketamine plus an oral antidepressant
- **SUSTAIN-3:** phase 3, long-term extension trial of esketamine plus an oral antidepressant



What were the results of the analysis?

Overall, mean age ranged from 41.8 to 47.3 years and most patients were female (57.8%–69.4%). Patients had TRD and moderate to severe depression in their current episode, with baseline MADRS total scores ranging from 29.1 to 37.6. Esketamine showed higher and sustained remission rates vs comparators. Treatment emergent adverse event rates were consistent with the known safety profile for ESK.

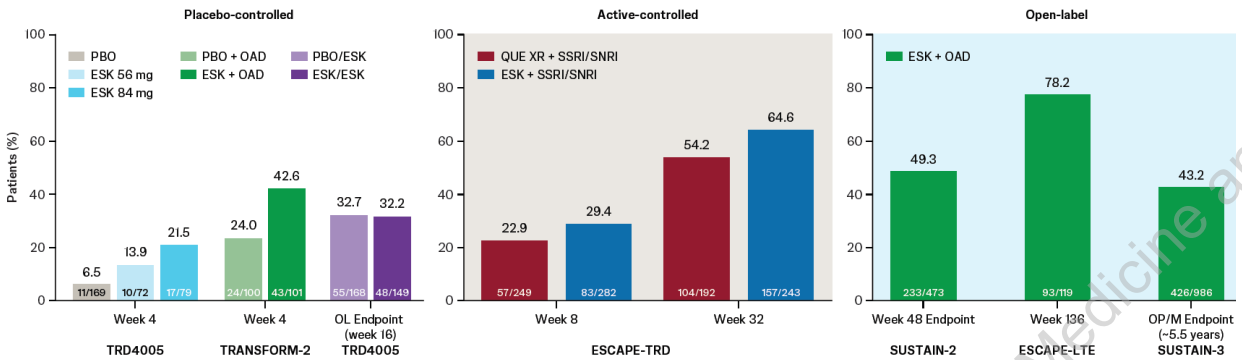
Baseline Symptom Rating Scale Scores



As monotherapy, remission rates (MADRS total score ≤ 10) ranged from 13.9% to 21.5% at week 4 and 32.2% at week 16.

As combination therapy (esketaamine nasal spray + OAD), remission rates (MADRS total score ≤ 10) ranged from 29.4% to 78.2% over treatment durations of up to 5.5 years.

Remission Rates (MADRS total score ≤ 10)



ESK, esketamine nasal spray; ESK/ESK: patients who received ESK after 4 weeks of ESK (56 mg or 84 mg); OAD, oral antidepressant; OP/M, optimization/maintenance phase; PBO, placebo nasal spray; PBO/ESK, patients who received treatment with ESK after 4 weeks of PBO; QUE XR, quetiapine extended-release; SNRI, serotonin-norepinephrine reuptake inhibitor; SSRI, selective serotonin reuptake inhibitor; TRD, treatment-resistant depression.

Treatment emergent adverse event (TEAE) rates were consistent with the known safety profile for ESK.

The most common TEAEs were:

- Dissociation – a mental state in which a person feels temporarily **detached from their thoughts, feelings, body, or surroundings**
- Nausea
- Dizziness
- Headache

What were the limitations of the analysis?

This analysis was not a formal meta-analysis and did not include pooled statistical comparisons across studies. Differences in trial designs limit direct comparisons. Additionally, remission definitions varied across studies, using MADRS thresholds of ≤ 10 or ≤ 12 , which further affects cross-trial interpretability.