

ENGAGE THERAPEUTICS

The Power to Stop Epileptic Seizures

Epilepsy is relentless. This promising rescue therapy could help.

In a Phase 2a proof of concept clinical study, Staccato Alprazolam stopped 80% of seizure-like activity within two minutes. It has the potential to be the first rescue treatment that can stop the progression of individual epileptic seizures.

We're seeking adults living with focal or generalized seizures for a Phase 2b clinical trial of Staccato Alprazolam in study sites across the United States. This clinical trial aims to assess the clinical feasibility, safety and efficacy of Staccato Alprazolam in treating an epilepsy seizure episode.

About Staccato Alprazolam

This seizure rescue treatment combines the FDA-approved Staccato inhaler device with Alprazolam, a well-known benzodiazepine that has potent anti-epileptic properties. It could be the first product approved to rapidly terminate seizure activity once it has begun.

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Phase 2b Clinical Trial Participant Eligibility Requirements

The Phase 2b study aims to assess the efficacy of Staccato Alprazolam in treating naturally occurring seizures. Criteria for participation includes:

- Age 18 years or older
- Diagnosis of focal or generalized epilepsy
- Documented history of seizure episodes that include at least one of the following:
- Generalized seizure episodes that start with a flurry of absence seizures or myoclonic seizures that last at least 5 minutes
- Episodes of prolonged focal seizures that last at least 3 minutes
- Episodes of 2 or more seizures within 2 hours

StATES (Staccato Alprazolam Terminates Epileptic Seizures) Clinical Trial Details

The trial is a double-blind, placebo-controlled, inpatient, dose-ranging efficacy study of Staccato Alprazolam (STAP-001) in subjects with epilepsy who have a predictable seizure pattern.

- 8 weeks in length, including the screening and follow-up periods.
- After an initial screening, seizure activity is followed for 4 weeks to confirm eligibility
- After the seizure event, the patient will be given one dose of STAP-001 or placebo and then will be followed for at least 24 hours after dosing
- Following discharge, a study coordinator will follow up with the participant via phone 12–16 days after the patient received the study drug (STAP-001) or placebo





