

Staccato Alprazolam Terminates Epileptic Seizures (StATES)



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focal or generalized epilepsy?**

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Study title: A Double-Blind, Placebo-Controlled, Inpatient, Dose-Ranging Efficacy Study of Staccato Alprazolam (STAP-001) in Subjects with Epilepsy with a Predictable Seizure Pattern

Simple title: Effectiveness of inhaled staccato alprazolam in treating an episode of focal or generalized seizures. This study is commonly referred to as **StATES** –(Staccato Alprazolam Terminates Epileptic Seizures).

What is this study about?

StATES is looking at how effective and safe orally-inhaled alprazolam (also known as STAP-001) is in people 18 years of age or older with focal or generalized epilepsy when given at the time of a seizure episode.

The following information will be gathered for each seizure episode and in the hours after the STAP-001 medication is given:

- If seizure activity was stopped within two minutes of giving STAP-001
- If seizures recurred within 2 to 12 hours after giving STAP-001
- The seizure severity
- If the seizure progressed to a complex partial (focal impaired awareness) or generalized tonic-clonic seizure



Participating in StATES will take place **partly** at an inpatient unit in a hospital. Participants will be admitted to a Clinical Research Unit (CRU) or an Epilepsy Monitoring Unit (EMU) for 2 to 8 days for the “treatment phase.” When they are hospitalized, they will be given a **one-time dose** of either the study drug (STAP-01) or a placebo treatment after a seizure takes place. The rest of StATES is done after the person is discharged from the hospital.

Who can participate?

Eligibility criteria includes:

- Age 18 years or older
- Diagnosis of focal or generalized epilepsy
- Documented history of predictable 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 multiple (2 or more) focal seizures within a 2-hour time period
- Able to provide personally signed and dated informed consent to participate in the study or will have a legally authorized representative sign the informed consent on their behalf

How can I participate?

- The study is about 8 to 12 weeks long, including the screening and follow-up periods.
- After an initial screening in an outpatient visit, you will be followed for 4 weeks to make sure you are eligible for the study. You would record your seizure activity in a daily seizure diary. If your seizure pattern qualifies, you will be randomly assigned (like flipping a coin) to either the study drug or a placebo. Neither you nor the study administrator will know which medicine you are getting.
- You will then enter a “treatment phase” and be admitted to a CRU or EMU in anticipation of a seizure. After you have a seizure event, you will be given one dose of STAP-001 or placebo. You will be followed for at least 12 hours after the medicine is given.
- Following discharge from the CRU or EMU, your last study visit will be done by a phone call with a study coordinator 12–16 days after you received the study drug (STAP-001).

Are there risks?

- People receiving benzodiazepine treatment (more than 4 times per week) or conditions such as severe cardiac (heart) and respiratory (breathing) disease are at higher risk for sedation from the medicine. These people will not be able to join StATES.
- Vital signs, heart rhythm, and brain activity will be monitored throughout the inpatient period of the study to monitor for sedation.

For more information on the study and how to join, please visit <http://www.epilepsystudy.com/>