

The EMBOLD Study Relutrigine (PRAX-562-221):

Advancing a clinical-stage, investigational treatment built for children with early-onset SCN2A and SCN8A developmental and epileptic encephalopathies (DEEs)



Purpose

A placebo controlled clinical trial to evaluate the safety and effectiveness of relutrigine (PRAX-562) in reducing seizures



Duration

Up to 22 weeks for part A, with an option to continue receiving relutrigine after the completion of the study



At home - fully remote

Choose between fully remote, in-clinic, or combined participation

Topline data from the first part of EMBOLD study in SCN2A and SCN8A DEE

46%
reduction

Children taking the study medication had nearly half as many seizures compared with those not taking it



About 1 in 3 children became completely free of seizures while taking the medication



Many children showed better alertness, communication, and less severe seizures

75%
reduction

Children who continued taking the medication for an extended period had even fewer seizures; about 3 out of 4 seizures were prevented



Based on these encouraging results, the next phase of the EMBOLD study for children with SCN2A and SCN8A DEEs has begun

Your child may be able to participate if they

- Are 2 through 18 years old
- Have received a diagnosis of
 - SCN2A gene mutation with onset of seizures in the first 3 months of life; or,
 - SCN8A gene mutation with seizures
- Have at least 8 motor seizures (seizures that involve movement) in the 4 weeks prior to screening
- Remain on up to two other sodium channel blockers

(for example, phenytoin, carbamazepine, oxcarbazepine, lacosamide) while trialing relutrigine; There is no cap on the number of other anti-seizure medications during the trial

Next Steps: To learn more about the EMBOLD study and to see if your child qualifies, visit www.emboldstudy.com

Relutrigine is an investigational drug and is not approved by any agency for use.

Placebo: A placebo is an inactive material that looks like relutrigine but does not contain any active study drug. Researchers use a placebo to see if the relutrigine works better or is safer than taking nothing.