Beeline: A Phase 3 Study in GRIN-related Neurodevelopmental Disorder

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 1 month to 18 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

Part A, Participant:

- Diagnosed with GRIN-NDD with GRIN1, GRIN2A, GRIN2B, or GRIN2D gene variants known to result in GoF of the NMDA receptor
- Phase 3 Cohort 1 (Qualifying Seizures Cohort) ONLY: Experiencing at least 1 CMS per week and ≥4 CMS (generalized or focal) during screening
- With history of inadequate response to at least 2 standard antiseizure medications (ASMs)
- Phase 3 Cohort 2 (Without Qualifying Seizures Auxiliary Cohort) ONLY: With significant neurodevelopmental symptoms and a GRIN-CGI-S score ≥4
- On a stable dose of standard ASMs for at least 4 weeks prior to screening and should remain on stable doses throughout study participation
- On stable nonpharmacological treatments such as ketogenic diet and should remain stable throughout study participation

Part B:

- Participant has completed Part A and is eligible to continue study participation according to the judgement of the investigator and sponsor.

Exclusion Criteria:

PART A, Participant:

- Has clinically relevant medical, neurologic, or psychiatric condition and/or behavioral disorder (including those related to GRIN-NDD) that would preclude or jeopardize participant's safe participation or study drug administration or the conduct of the study according to the judgement of the investigator or sponsor.
- Is receiving >4 standard ASMs at screening
- Has a body weight of less than 5 kg at screening

Part B:

- Participant has clinically relevant medical, neurologic, or psychiatric condition and/or behavioral disorder (including those related to GRIN-NDD) that would preclude or jeopardize participant's safe participation of study drug administration or the conduct of the study according to the judgement of the investigator or sponsor.

Conditions & Interventions

Interventions:
DRUG: Radiprodil, DRUG: Placebo
Conditions:
GRIN-related Neurodevelopmental Disorder
Keywords:
Beeline, GRIN1, GRIN2A, GRIN2B, GRIN2D, GRIN-NDD

More Information

Description:
The Phase 3 portion of Study RAD-GRIN-101 is a multinational, multicenter, randomized, double-blind, placebo-controlled trial followed by an open-label extension to evaluate the efficacy and safety of radiprodil in participants with GRIN-related neurodevelopmental disorder (GRIN-NDD) with a gain-of-function (GoF) genetic variant. This study will enroll two cohorts: one cohort of participants with a minimal number of countable motor seizures (with or without behavioral symptoms) (Phase 3 Cohort 1: Qualifying Seizures Cohort); and a second cohort with disease symptoms but no seizures or fewer seizures than required for the Qualifying Seizures Cohort (Phase 3 Cohort 2: Without Qualifying Seizures Auxiliary Cohort). Participants in each cohort will be randomized 1:1 to receive active drug (radiprodil) or matching placebo (Part A). Following completion of Part A, all eligible participants (including those previously on placebo) may continue into the open-label extension period (Part B) to receive radiprodil. The placebo-controlled portion is expected to be approximately 16 weeks for participants in Phase 3 Cohort 1 and 28 weeks for participants in Phase 3 Cohort 2. The study will evaluate the effect of radiprodil on seizures and non-seizure symptoms and assess safety.

Contact(s): Katie Hall - Katie.Hall@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE3
IRB Number:
System ID: NCT07224581

Thank you for choosing StudyFinder. Please visit http://studyfinder.cchmc.org to find a Study which is right for you and contact clinicalstudies@cchmc.org if you have questions or need assistance.