Evaluation of IV AMBTX-01 (Neridronate) for Treatment of CRPS Type 1 (CRPS-RISE)

NCT07210515

Status	RECRUITING
Phase	Phase 3
Sponsor	Ambros Therapeutics, Inc.
Enrollment	270 participants

Key Eligibility Criteria

Inclusion (16)

- Male or female participant e 18 years of age at time of Screening.
- A diagnosis of CRPS-1 according to the clinical Budapest Criteria as recommended by the International Association for the Study of Pain (IASP), as well as no known peripheral nerve injury. Signs and symptoms of CRPS must apply to a single identified affected limb (i.e., arm, hand, wrist, leg, ankle or foot) and must demonstrate asymmetry with respect to the contralateral limb.
- Single affected limb at the Screening and Randomization Visits meeting the following warm subtype criteria:
- Edema in the affected limb
- AND e 2 of the following:

... and 11 more (see full listing online)

Exclusion (12)

- A current or prior diagnosis of CRPS Type 2 or CRPS not otherwise specified (CRPS NOS), or whose CRPS has no known inciting event, or CRPS-1 without criteria of the warm subtype at the time of Screening.
- e 40points on the Pain Catastrophizing Scale.
- Prior use of neridronate or participation in a clinical study where the participant may have received neridronate.
- Participants currently taking or planning to be treated with prohibited concomitant medications/therapies, or not likely able to follow the protocol restrictions for use of concomitant treatment.
- Severely impaired renal function.

... and 7 more (see full listing online)

Locations (4 total)

Ambros Clinical Trial Site, Phoenix, Arizona, United States
Ambros Clinical Trial Site, Tucson, Arizona, United States
Ambros Clinical Trial Site, Tustin, California, United States
... and 1 more locations