(2R,6R)-Hydroxynorketamine for the Treatment of Neuropathic Pain

NCT05864053

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Rush University Medical Center
Enrollment	25 participants

Key Eligibility Criteria

Inclusion (11)

- Adult patients (18 to 75 years) with an established diagnosis of chronic (\> 3 month) NP of the extremities.
- Presence of NP as determined at screening using the 10 item Neuropathic Pain Questionnaire (DN4), with a score of e4 required for study inclusion.
- Ability to read and write English sufficiently to complete study related procedures.
- A body mass index (BMI) (weight \[kg\]/height\[m \]) between 18 and 35 kg/m (inclusive) and weighs between 50 kg and 120 kg (110 - 264 pounds).
- Blood pressure with subject is in a supine position for approximately 5 minutes between 90 and 145 mmHg systolic and no higher than 90 mmHg diastolic at baseline.

... and 6 more (see full listing online)

Exclusion (15)

- Subjects with suspected increased intracranial or intraocular pressure.
- Subjects that have previously received ketamine for the treatment of a chronic pain diagnoses.
- Previous or current participation in any clinical study with an investigational drug, device, or biologic within 30 days.
- Subjects with severe medical illness including (but not limited to) hepatic, cardiovascular, pulmonary, renal, hematologic, endocrine, gastrointestinal, immunologic, dermatologic, neurologic, oncologic, or psychiatric disease that in the opinion of the PI would endanger the safety of the subject or the validity of the study results.
- Clinically significant acute illness in the 2 weeks prior to dosing.

... and 10 more (see full listing online)

Locations (1 total)

Rush University Medical Center, Chicago, Illinois, United States