

# Evaluating the Safety and Efficacy of Polyethylene Glycol (PEG) Mediated Fusion (PEG Fusion)

**Status:** RECRUITING

## Eligibility Criteria

**Age:** 18 years to 80 years old

This study is NOT accepting healthy

**Healthy Volunteers:** volunteers

### Inclusion Criteria:

1. Ages 18-80 2. Sustained a complete peripheral nerve injury resulting from upper extremity trauma presenting within 48 hours of injury 3. Involves injury or dysfunction to motor and/or sensory function of the axillary, radial, median, ulnar, or musculocutaneous nerve with injury localized between the proximal humerus and the distal flexion crease of the wrist 4. Involves a "mixed" nerve segment (i.e., involves a location of any of the above specified nerves that can be expected to have both sensory and motor axons present).

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### Exclusion Criteria:

1. Patients beginning surgery within hours after injury. 2. Injury to the brachial plexus nerves 3. Injury to the nerves distal to the distal flexion crease of the wrist 4. Injury that involves a distal extension of the parent nerve that is considered sensory only (superficial radial nerve, lateral antebrachial cutaneous nerve, etc.) or the posterior interosseus or anterior interosseus nerve distal to the midpoint of the forearm (i.e., distal to what can be considered the main motor branches of the PIN and AIN). 5. Previous peripheral nerve injury resulting from trauma, stroke, muscular, neurologic, or neuromuscular disorder 6. Documented psychiatric disorder that is expected to result in high probability of self-harm or interfere with study follow-up. 7. Severe problems with maintaining follow up (e.g., patients who are prisoners or homeless at time of injury or who are intellectually challenged without adequate family support). 8. Not expected to survive the next 30 days due to their injuries/health condition. 9. The subject has a known allergy to polyethylene glycol (PEG). 10. If any of the assessments cannot be done on the contralateral side (CL) or the MRCC sensory 2PD value is  $\geq 10$  mm on the CL side during baseline period, the subject is a screen failure. 11. The subject is pregnant and/or is breastfeeding. 12. The subject has a significant medical comorbidity precluding immediate repair. 13. The subject is not able to strictly adhere to the rules of the current clinical protocol.

## Conditions & Interventions

### Interventions:

DRUG: NTX-001

### Conditions:

Peripheral Nerve Injuries

## More Information

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**Principal Investigator:**

**Phase:** PHASE2

**IRB**

**Number:**

**System ID:** NCT04789044

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