

Phase 1b/2a Clinical Trial to Determine the Safety, Tolerability and Efficacy of TZ-161 in Spinal Cord Injury

NCT06677229

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Technophage, SA
Enrollment	28 participants

Key Eligibility Criteria

Inclusion (8)

- Subjects aged 18-65 years old.
- Subjects with clinical diagnosis of acute SCI that comply with the following:
- Injury located on the thoracic region (T1 to T12).
- With clinical suspicion of a single traumatic (contusion) lesion.
- AIS grade of grade B, C or D with a motor score less than or equal to 3 in at least one key muscle of a lower limb.

... and 3 more (see full listing online)

Exclusion (30)

- Clinical or imaging suspicion of multi-lesion or extra-thoracic contusions on diagnostic CT scan and on MRI at 48H*.
- Subjects in coma or with significant cognitive impairment in the opinion of the investigator.
- Subjects presenting mechanical ventilation dependence.
- Subjects with past medical history of any - structural - neurological disorder of the central or peripheral nervous system, including past spinal cord injury. Furthermore, subjects with spine/bone-related medical history (prior to SCI) that in the opinion of the investigator are not yet resolved or previous lesions that are located in the same area of the study SCI should also be excluded.
- Subjects with dysphagia or inability to swallow tablets.

... and 25 more (see full listing online)

Locations (2 total)

Hospital Universitario Reina Sofia, Córdoba, Spain
Hospital Universitario La Paz, Madrid, Spain