ISSN: 2641-0362

MEDDOCS Open Access Publisher

Neurology and Neurological Sciences: Open Access

Open Access | Research Article

Lami-Stem™ Technology for Functional Recovery in Chronic Thoracic Spinal Cord Injury: A Prospective Interventional Study in 45 Patients

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Received: May 22, 2026

Accepted: June 05, 2026

Published Online: June 12, 2026

Journal: Neurology and Neurological Sciences: Open Access
Publisher: MedDocs Publishers LLC

Online edition: http://meddocsonline.org/

Keywords: Spinal cord injury; Stem cell therapy; Neuroregeneration; Mesenchymal stem cells; Neurorehabilitation; Lamistem technology; Regenerative medicine.

Abstract

Background: Spinal Cord Injury (SCI) remains a devastating neurological disorder that frequently results in permanent motor, sensory, and autonomic impairment. Despite advances in surgical stabilization and neurorehabilitation strategies, effective regenerative therapies capable of restoring neurological function remain limited. Stem cell–based therapies have emerged as promising approaches for promoting neurodegeneration, reducing inflammation, and enhancing neural plasticity. However, clinical outcomes remain inconsistent due to hostile inflammatory microenvironments within injured spinal tissue. Lamistem™ technology represents a novel regenerative platform combining mesenchymal stem cells with biomolecular scavenger cells designed to neutralize inflammatory mediators and oxidative stress within injured neural tissue.

Objective: To evaluate the safety and therapeutic efficacy of Lamistem™ technology in patients with chronic thoracic spinal cord injuries below the T10 level.

Methods: A prospective interventional clinical study was conducted involving 45 patients diagnosed with chronic spinal cord injuries below T10. Each participant received 120 million mesenchymal stem cells administered via intraspinal injection, combined with 10 million biomolecular scavenger cells designed to reduce inflammatory microenvironmental factors.

Cells were delivered through a multimodal administration strategy, including:

- Intraspinal injection
- Intravenous infusion
- Intramuscular delivery

Cite this article: Majumdar P, Ahemad N, Aliyeva A, Kaura S, Alekbarli K, Jafarova U. Lami-Stem™ Technology for Functional Recovery in Chronic Thoracic Spinal Cord Injury: A Prospective Interventional Study in 45 Patients. Neurol Neurol Sci Open Access. 2026; 9(1): 1038.

Following the initial regenerative intervention, patients underwent two months of intensive neurorehabilitation therapy. After completion of rehabilitation, a second Lamistem™ treatment cycle was administered using the same protocol. Clinical outcomes were evaluated using standardized mobility indices, standing balance assessment, postural stability measures, and lower-limb strength evaluation.

Results: All 45 patients completed the treatment and follow-up protocol. Significant improvements were observed across multiple functional parameters. Mean mobility scores improved by up to 55%, while standing balance and postural stability improved by approximately 50% and 47% respectively. Several patients demonstrated increased voluntary muscle activation in the lower limbs and improved ability to maintain standing posture with assistance. No major adverse events or serious neurological complications were reported.

Conclusion: Lamistem™ regenerative therapy demonstrated encouraging outcomes in patients with chronic thoracic spinal cord injury. The combination of stem cells with biomolecular scavenger therapy may enhance neural repair by improving the injury microenvironment and supporting neuroplasticity. These findings support further investigation through randomized controlled trials with larger cohorts to confirm therapeutic efficacy and long-term safety.

Introduction

Spinal Cord Injury (SCI) represents one of the most devastating neurological conditions, often resulting in permanent disability and profound impairment in quality of life. Worldwide, the incidence of spinal cord injury ranges from 10 to 80 cases per million individuals annually, with thoracic injuries accounting for a significant proportion of cases [1]. SCI typically results from traumatic events such as motor vehicle accidents, falls, sports injuries, and violence. The neurological consequences of SCI often include paralysis, loss of sensory function, autonomic dysregulation, and chronic pain [2].

The pathophysiology of spinal cord injury involves two major phases:

Primary injury: The primary injury occurs at the moment of trauma and involves mechanical disruption of neuronal axons, blood vessels, and supporting structures of the spinal cord [1,3].

Secondary injury: The secondary injury cascade involves complex biochemical and cellular processes, including:

- Neuroinflammation
- Excitotoxicity
- Oxidative stress
- Apoptotic cell death
- Demyelination
- Formation of inhibitory glial scars

These processes collectively create a hostile microenvironment that prevents effective neuronal regeneration [3,4].

Conventional treatment approaches focus primarily on stabilization of the spine, prevention of secondary complications, and long-term rehabilitation. However, these strategies rarely result in substantial neurological recovery [5].

In recent years, regenerative medicine has introduced new therapeutic possibilities through stem cell–based interventions. Mesenchymal Stem Cells (MSCs) are particularly attractive due to their:

- Immunomodulatory properties
- Secretion of neurotrophic factors
- Ability to promote angiogenesis
- Potential to enhance neuroplasticity

However, the survival and integration of transplanted stem cells are often limited by the inflammatory microenvironment present at injury sites [6].

To address these limitations, Lamistem™ technology was developed as a combinatorial regenerative approach. This platform integrates mesenchymal stem cells with biomolecular scavenger cells designed to neutralize inflammatory cytokines and oxidative molecules that inhibit neural repair [5,7].

The present study evaluates the clinical outcomes of Lamistem™ regenerative therapy in 45 patients with chronic spinal cord injuries below the T10 level.

Methods

Study Design: This investigation was designed as a prospective interventional clinical study evaluating the therapeutic effects of Lamistem™ regenerative therapy in chronic spinal cord injury patients. The study was conducted in accordance with ethical standards and followed principles consistent with the Declaration of Helsinki.

Patient Population: A total of 45 patients diagnosed with chronic spinal cord injury below T10 were enrolled.

Inclusion Criteria: Patients were eligible for inclusion if they met the following criteria (Figure 1).

- Age between 18 and 65 years
- Chronic spinal cord injury duration greater than 6 months
- Neurological injury below the T10 level
- Stable medical condition
- Ability to participate in rehabilitation therapy

Exclusion Criteria: Patients were excluded if they had:

- Active systemic infections
- Malignancy
- Severe organ dysfunction
- Unstable spinal fractures
- Pregnancy

Lamistem™ treatment protocol

The Lamistem™ therapy consisted of a combination regenerative intervention involving stem cells and biomolecular scavenger cells.

Stem cells: Each patient received 120 million mesenchymal stem cells prepared under controlled laboratory conditions.

Biomolecular scavenger cells: In addition to stem cells, 10 million biomolecular scavenger cells were administered to modulate inflammatory and oxidative pathways within the injured spinal cord.

Administration routes: The regenerative cells were delivered through a multimodal administration approach, including all three ways for each patient:

1. *Intraspinal Injection*: Direct injection at the injury level to maximize local regenerative effects.
2. *Intravenous Infusion*: Systemic delivery aimed at supporting broader neuroregenerative signalling.
3. *Intramuscular Injection*: Peripheral administration intended to stimulate neuromuscular recovery.

Rehabilitation program: Following the first regenerative intervention, patients participated in two months of structured neurorehabilitation therapy.

The rehabilitation program included:

- Neuromuscular stimulation
- Assisted gait training
- Core strengthening exercises
- Postural control training
- Balance stabilization therapy

Rehabilitation sessions were conducted five days per week under clinical supervision.

Second Treatment Cycle: After completion of the rehabilitation phase, post 3 months patients received a second Lamistem™ regenerative treatment following the same administration protocol.

Outcome measures

Clinical outcomes were evaluated using multiple functional parameters.

Primary Outcomes

- Mobility improvement
- Standing balance
- Postural stability

Secondary Outcomes

- Lower limb strength
- Weight-bearing capacity
- Functional independence

Patients were followed for 6 to 12 months following the final treatment.

Statistical analysis: Statistical analysis was performed using SPSS version 26.0 (IBM Crop., USA). Continuous variables were expressed as mean ± standard deviation. Changes in functional outcomes including's standing ability, balance performance, and postural stability were evaluated using repeated- measures Analysis of Variance (ANOVA). When significant differences were identified, post hoc pairwise comparisons were conducted using Bonferroni correction to determine differences between baseline and follow up time points. A p- value <0.05 was considered statistically significant. Categorical variables were analysed using chi-square test where appropriate.

Comparisons between baseline and post-treatment outcomes were evaluated using:

- Paired t-tests
- Repeated measures ANOVA

p-value less than 0.05 was considered statistically significant.

Neurological Observations

Several patients demonstrated:

- Voluntary contraction of lower limb muscles
- Improved trunk control
- Enhanced ability to maintain standing posture

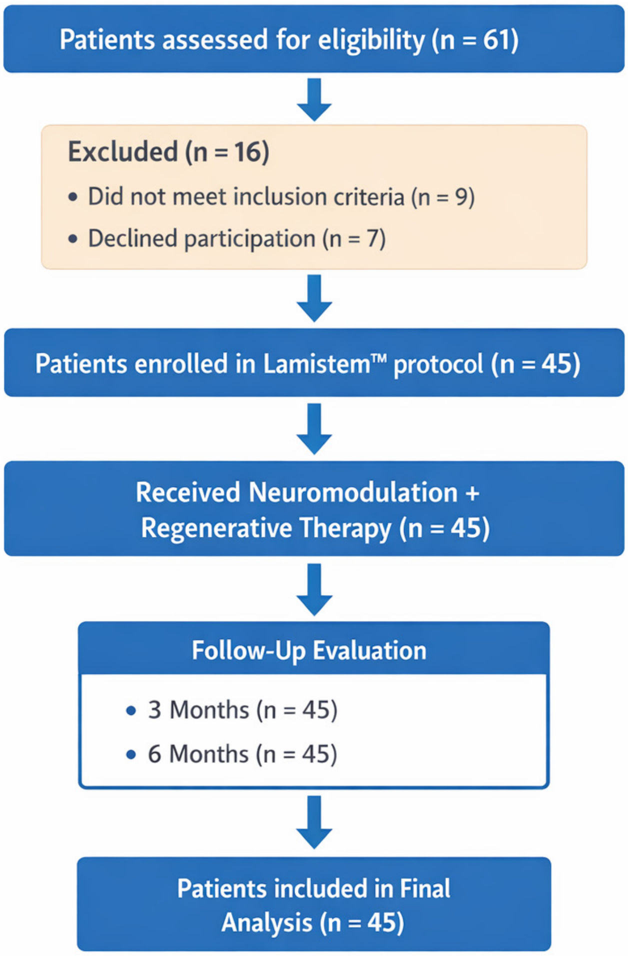


Figure 1: CONSORT style flow diagram demonstrating screening, enrolment, treatment allocation, and follow-up of the patients undergoing Lami-Stem neuromodulation therapy for chronic spinal cord injury.

Result

Patient enrolment and study completion: A total of 45 patients with chronic thoracic spinal cord injuries below the T10 level were enrolled in the study. All patients met the predefined inclusion criteria and successfully completed both cycles of the Lamistem™ regenerative therapy protocol, including the two-month neurorehabilitation program between treatment phases. No participants were lost to follow-up during the observation period. The mean age of participants was 38.2±9.4 years, with 30 male and 15 female patients included in the cohort. The average duration of injury prior to treatment initiation was 2.8±1.6 years, indicating a population with established chronic spinal cord injury (Table 1).

Table 1: Patient Demographics.

Parameter	Value
Total Patients	45
Mean Age	38.2 ± 9.4 years
Male	30
Female	15
Mean injury duration	2.8 years

Functional mobility outcomes: Significant improvements in mobility were observed following Lamistem™ therapy combined with structured rehabilitation. The mean baseline mobility score improved from 28.4±6.2 at baseline to 44.1±7.5 following completion of the second treatment cycle, representing an approximate 55% increase in functional mobility. Many patients demonstrated improved voluntary movement in the lower limbs, with several participants progressing from assisted sitting balance to partial standing capability with support. Improvements were particularly noticeable during rehabilitation exercises requiring coordinated trunk and lower extremity control. Statistical analysis confirmed that the improvement in mobility scores was highly significant ($p<0.001$) (Table-2).

Table 2: Functional outcome.

Outcome Parameter	Baseline	Post Treatment	Improvement	P value
Mobility Score	28.4	44.1	55%	<0.001
Standing Balance	30.2	45.3	50%	<0.001
Postural Stability	27.5	40.4	47%	<0.001
Weight Bearing Strength	29.3	44.5	52%	<0.001

Standing, balance and postural stability: Substantial improvements were also observed in standing balance and postural control following the regenerative therapy protocol. The mean standing balance score increased from 30.2±5.8 at baseline to 45.3±6.4 post-treatment, corresponding to an approximate 50% improvement. Patients exhibited enhanced trunk stability and improved ability to maintain upright posture during assisted standing exercises. In several cases, individuals who previously demonstrated poor postural control were able to sustain standing positions for longer durations following treatment and rehabilitation. Postural stability measurements improved from 27.5±6.1 at baseline to 40.4±6.8 after treatment, representing an overall 47% improvement ($p<0.001$) (Figure 2).

Weight-bearing strength and neuromuscular activation: Evaluation of lower limb strength and weight-bearing capacity revealed meaningful improvements following the treatment protocol. The mean weight-bearing strength score increased from 29.3±5.9 at baseline to 44.5±7.2 after therapy, reflecting an approximate 52% improvement. Electrophysiological and clinical observations during rehabilitation sessions indicated enhanced voluntary muscle activation in the lower extremities in multiple patients. Improvements in neuromuscular coordination were also noted during assisted gait training exercises. These findings suggest that the regenerative therapy protocol may have contributed to improved neural signalling and functional muscle recruitment (Figure 2).

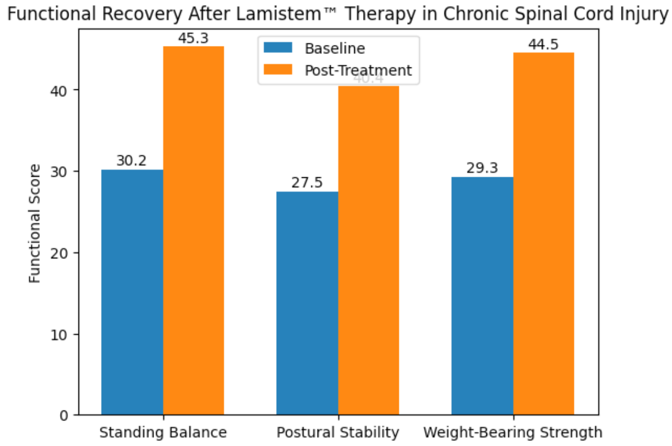


Figure 2: Patients with chronic thoracic spinal cord injury demonstrated significant functional improvements following functional improvements following Lami-Stem therapy and structured rehabilitation. Standing balance improved from 30.2 to 45.3, postural stability from 27.5 to 40.4, and weight bearing strength from 29.3 to 44.5, indicating substantial recovery in neuromuscular control and postural function.

Subgroup observations based on injury duration: Exploratory subgroup analysis suggested that patients with shorter injury duration (<3 years) demonstrated slightly greater functional improvement compared with those with longer-standing injuries. These patients showed faster progression during rehabilitation exercises and more noticeable improvements in balance and voluntary muscle activation. However, meaningful improvements were still observed across the entire cohort regardless of injury duration. Further studies with larger sample sizes are required to confirm whether injury chronicity significantly influences treatment response.

Safety and tolerability: The Lamistem™ therapy protocol was generally well tolerated among the study participants. No serious adverse events were reported throughout the treatment and follow-up period. Minor side effects were observed in a small number of patients and included temporary injection site discomfort in five patients and mild transient fever in two patients, which resolved spontaneously without medical intervention. These findings suggest that the regenerative therapy protocol demonstrated a favourable safety profile within the observed cohort (Table 3).

Table 3: Safety outcomes.

Adverse Event	Patients
Injection Discomfort	5
Transient fever	2
Neurological deterioration	0
Severe infection	0

Discussion

The results of this study demonstrate encouraging therapeutic potential for Lamistem™ regenerative technology in patients with chronic thoracic spinal cord injury. The functional improvements observed in mobility, standing balance, and postural stability suggest that the combination of stem cells and biomolecular scavenger therapy may enhance neural repair processes.

Neurophysiological improvements and rehabilitation milestones:

In addition to improvements in clinical mobility scores, several patients demonstrated observable neurophysiological changes during the rehabilitation phase following Lamistem™ therapy. During structured rehabilitation sessions, therapists reported progressive increases in voluntary muscle engagement in the lower extremities, particularly in muscle groups responsible for hip stabilization, quadriceps activation, and trunk support [8,9].

Patients who initially demonstrated limited or absent voluntary movement in the lower limbs began to show gradual neuromuscular activation during assisted exercises, suggesting possible restoration of neural signaling pathways or enhancement of residual spinal cord circuitry. Improvements in trunk stability and core muscle control were also observed in a substantial proportion of participants [10,11].

During balance training exercises, patients demonstrated improved postural reflex responses, allowing them to maintain upright seated or supported standing positions for longer durations compared to baseline assessments. Several patients progressed from requiring maximal assistance during standing exercises to partial weight-bearing with minimal assistance [12].

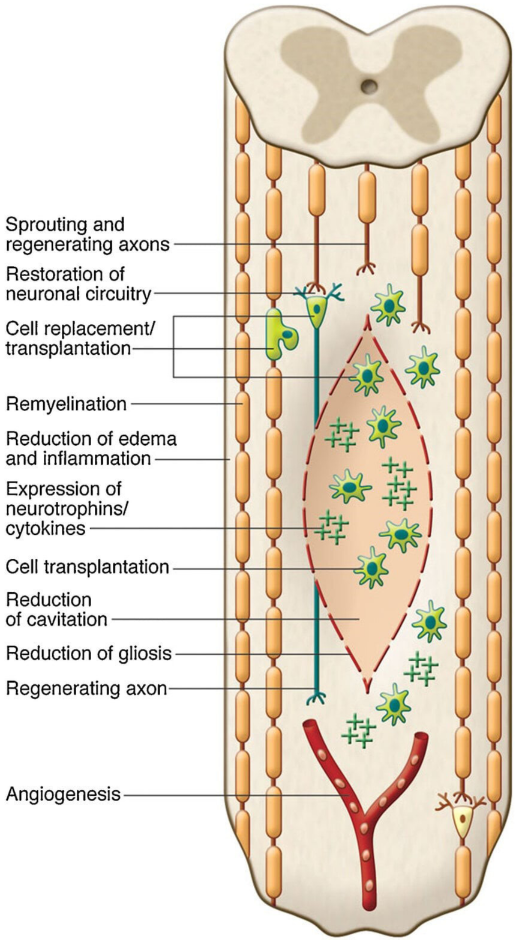


Figure 3: Potential mechanisms of spinal cord repair following stem cell transplantation. The diagram shows some of the potential mechanisms of repair after transplantation of stem cells into the injured cord. Potential mechanisms include replacement of oligodendrocytes or neurones by transplanted cells (shown in green), remyelination of the spared axons, restoration of the neural circuitry, enhanced preservation of host neuronal and glial cells, bridging the cavity by transplanted cells and creation of favourable environment for plasticity and axonal regeneration.

The rehabilitation team also reported improvements in coordination during assisted gait training, where patients were able to initiate stepping movements with improved rhythmicity and muscular engagement. These observations suggest that regenerative therapy combined with intensive neurorehabilitation may facilitate reactivation of dormant neural pathways and spinal locomotor networks. Although electrophysiological testing was not the primary outcome measure of the present study, clinical observations during rehabilitation indicated patterns consistent with enhanced neuromuscular integration and neuroplastic adaptation (Figure 3) [11,15].

Mechanistic interpretation of functional recovery:

The functional improvements observed in this cohort may be explained by several biological mechanisms associated with stem cell–mediated neuroregeneration and microenvironment modulation. Mesenchymal stem cells are known to release a wide range of neurotrophic and growth factors, including Brain-Derived Neurotrophic Factor (BDNF), Nerve Growth Factor (NGF), and Vascular Endothelial Growth Factor (VEGF). These molecules can promote neuronal survival, stimulate axonal sprouting, and enhance synaptic plasticity within injured neural networks [13].

In addition to paracrine signaling effects, the inclusion of biomolecular scavenger cells within the Lamistem™ platform may contribute to the reduction of oxidative stress and inflammatory cytokine activity within the spinal cord injury microenvironment. By neutralizing reactive oxygen species and inflammatory mediators, these scavenger biomolecules may help create a more permissive biological environment for neural repair and axonal regeneration [14].

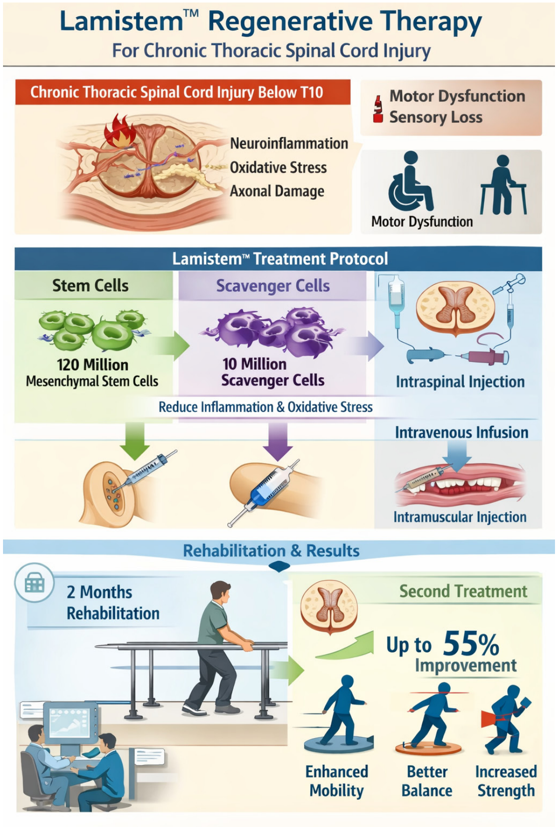
Furthermore, the multimodal delivery strategy employed in the present study—combining intraspinal, intravenous, and intramuscular administration routes—may enhance both localized and systemic regenerative signaling. Intraspinal delivery provides targeted regenerative support directly at the injury site, while intravenous and intramuscular administration may facilitate broader neurotrophic and neuromuscular interactions. The structured neurorehabilitation program performed between treatment cycles likely played a critical role in reinforcing regenerative processes through activity-dependent neuroplasticity. Repetitive motor training and balance exercises can stimulate neural circuit reorganization and strengthen newly formed synaptic connections. Together, these mechanisms may act synergistically to promote the functional recovery observed in mobility, balance, and standing strength within the treated cohort (Figure 3) [15].

Limitations

Despite promising results, several limitations should be acknowledged:

- Absence of randomized control group prevents definite causal inference regarding the therapeutic effect of the Lami-Stem protocol.
- Moderate sample size of 45 patients, which may limit the generalizability of the findings.
- Single-centre study design
- Limited long-term follow-up

Future multicentre randomized controlled trials with larger patient cohorts and extended follow up periods are necessary to validate these preliminary findings.



Conclusion

Lami-Stem neuromodulation protocol demonstrated promising clinical benefits in patients with chronic spinal cord injury below the T10 level. Significant improvements were observed in standing ability, balance and postural stability during the six month follow up period. The therapy was well tolerated with no major adverse events reported. These preliminary finding suggest that neuromodulation assisted regenerative strategies like the integration of stem cells with biomolecular scavenger therapy may represent a novel therapeutic strategy capable of enhancing neural regeneration and functional recovery. Further controlled clinical trials are required to validate these findings.

Author declarations

Ethical approval

Nurax Clinics- India and Azerbaijan (NU-18/02/PM/2025).

Manuscript preparation and authors participation

P.M: Manuscript, Study design, Analysis, Observation, **N.A**: Manuscript, **S.K**: Analysis, **A.A**: Analysis, Observation, **U.J**: Manuscript, Observation.

Consent to participate

Informed consent was prepared for all induvial participants and will be obtained from all individual participants who are included in this study.

Human ethics and consent to participate declaration

This study was designed in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments. Informed consent was prepared to obtain from all individual participants who will be included in this study.

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