

# The role of early surgery in patients paralysed following injury

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<b>Registration date</b> 28/05/2009	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 28/10/2022	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**

The efficacy of surgical decompression before 24 hours versus 24 to 72 hours in patients with spinal cord injury from T1 to L1 - with specific consideration on ethics: a randomised controlled trial

**Acronym**

24.72HSCITL

**Study objectives**

The role and timing of surgical decompression after an acute spinal cord injury (SCI) remains one of the most controversial topics pertaining to spinal surgery. Blunt spinal trauma complicated by injury to the spinal cord most frequently occurs in the young male patient. The lack of controlled, prospective, multicenter clinical studies has contributed to confusion regarding optimal treatment methods for patients with injuries to the spinal cord. The spinal cord is vulnerable to injury resulting from high-energy motor vehicle collisions and falls. Regarding location of spinal cord, cervical and thoracolumbar area can be selected. This RCT tries to evaluate the thoracolumbar cord which we evaluated this area in previous retrospective studies. Thus, we chose patients with acute spinal cord injury from T1 to L1.

Hypothesis: first 24 hours surgical decompression is more effective than 24-72 hours in neurological improvement in the setting of traumatic spinal cord injury from T1 to L1.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

1. Ethics Committee of the Sina Trauma and Surgery Research Centre, Tehran University of Medical Sciences, approved on the 3rd June 2008 (ref: 15)
2. Ethics Committee of the Shahid Beheshti University of Medical Sciences, approved on the 28th October 2007 (ref: 44)

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Spinal cord injury (SCI)

**Interventions**

Surgical decompression of compressed spinal cord and stabilisation. This intervention is performed in both groups of early and so called late decompression. Because surgical technique varies according to the location of injury in the spine and the nature of the injury, surgeons are not restricted in their surgical technique.

**Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

To determine whether early or late surgical decompression is effective in neurological improvement in the setting of traumatic spinal cord injury from T1 to L1, assessed at all clinical assessment timepoints.

## **Key secondary outcome(s)**

1. To compare the neurological improvement in summed ASIA motor scores 12 months following a complete SCI in each of the early and late group of decompression
2. To compare the neurological improvement in summed ASIA motor scores 12 months following an incomplete SCI in each of the early and late group of decompression
3. To assess the extent of neural canal decompression in each of the early and late group of decompression
4. To assess fusion success in each of the early and late group of decompression
5. To assess sagittal alignment at fracture level in each of the early and late group of decompression
6. To compare the duration of acute hospitalization in each of the early and late group of decompression
7. To compare the overall length of acute hospital stay in each of the early and late decompression
8. To compare the overall length of chronic hospital stay for rehabilitation [22] in each of the early and late decompression
9. To assess the incidence of mortality in each of the early and late group of decompression
10. To determine frequency of complications in each of the early and late group of decompression

## **Timepoints of assessment:**

1. First clinical assessment: At the time of admission
2. Second clinical assessment: In the last hour before operation
3. Third clinical assessment: Immediately after operation and awakening from anaesthesia
4. Fourth clinical assessment: Six weeks after operation
5. Fifth clinical assessment: Six months after operation
6. Sixth clinical assessment: 12 months after operation
7. Seventh clinical assessment: The most recent follow-up

## **Imaging check up:**

First: Before operation

Second: Within a maximum of 7 days after operation

Third: 12 months after operation

Each of the other secondary outcome measures is evaluated at least twice: first before operation and 12 months after operation.

## **Completion date**

21/05/2013

## **Eligibility**

**Key inclusion criteria**

1. Both males and females, 18 years or older
2. Spinal cord injury between T1 and L1 of traumatic etiology
3. Haemodynamically stable
4. Spinal cord compression on magnetic resonance imaging (MRI)
5. Between 0 hours and 24 hours post-injury

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

73

**Key exclusion criteria**

1. Subjects with major and current psychiatric illness
2. Significant traumatic brain injury associated with the spinal cord injury
3. Major concurrent medical disease (including myocardial infarction within 3 months, uncompensated congestive heart failure, active systemic cancer, acquired immune deficiency syndrome [AIDS], diabetes mellitus)
4. Pre-injury major neurologic deficits or disease (e.g., stroke, Parkinson's disease, syringomyelia, Guillian-Barre)
5. Ankylosing spondylitis
6. Penetrating injuries to the thoracolumbar
7. Pregnant females
8. Life-threatening injuries which prevent early decompression of the spinal cord
9. Criminals
10. Under indictment or incarceration
11. Substance abuse
12. American Spinal Injury Association (ASIA) Impairment Scale category of E
13. No cord compression on MRI
14. Presence of spinal shock
15. Any cognitive deficit
16. Unable to provide informed consent
17. An injury which involves more than two adjacent vertebral levels

Selected participants are thoroughly informed of the trial and its attendant risks and asked to consent to be in one of two groups, those operated urgently in less than 24 hours from trauma or the late group who are operated and decompressed between 24 and 72 hours from trauma.

**Date of first enrolment**

22/05/2009

**Date of final enrolment**

21/05/2013

## Locations

**Countries of recruitment**

Iran

**Study participating centre**

**Research Centre for Neural Repair**

Tehran

Iran

11365-3876

## Sponsor information

**Organisation**

Sina Trauma and Surgery Research Centre (Iran)

**ROR**

<https://ror.org/01jqdqz10>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Sina Trauma and Surgery Research Centre, Tehran University of Medical Sciences (Iran) (Grant number: 76) (date confirmed: 3rd June 2008)

**Funder Name**

Shahid Beheshti University of Medical Sciences (Iran) (Grant number: 400/6691) (date confirmed: 18th January 2009)

# Results and Publications

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		18/09/2020	28/10/2022	Yes	No
<a href="#">Protocol article</a>	protocol	24/08/2009		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes