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The role of early surgery in patients paralysed following injury

Submission date	Recruitment status
06/05/2009	No longer recruiting
Registration date	**Overall study status**
28/05/2009	Completed
Last Edited	**Condition category**
28/10/2022	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
22/05/2009

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
328

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, Guilian-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
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Sponsor information

Organisation
Sina Trauma and Surgery Research Centre (Iran)

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Sponsor type
University/education

Website
http://www.sinatrc.ac.ir/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	24/08/2009		Yes	No
Results article		18/09/2020	28/10/2022	Yes	No