

American Spinal Injury Association (ASIA) motor, functional and health related quality of life outcome in traumatic Central Cord Syndrome, a prospective randomized Study

Submission date 16/05/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/06/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/10/2021	Condition category Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

H-28962

Study information

Scientific Title

American Spinal Injury Association (ASIA) motor, functional and health related quality of life outcome in traumatic Central Cord Syndrome, a prospective randomized Study

Acronym

CCSS

Study objectives

In acute traumatic central cord syndrome, surgical decompression of the spinal cord within 5 days will result in more rapid motor recovery, than decompression 6 weeks following injury.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Human Research Protection Office, Health Science Facility I (HSFI), School of Medicine University of Maryland (Baltimore, Maryland), approved on 14 May 2007.

Study design

Single center, prospective, randomized study.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Traumatic Central Cord Syndrome

Interventions

30 patients (15 patients in each group) will undergo standard surgical decompression of spinal cord either within the first 5 days or at 6 weeks following spinal cord injury. Each of the 15 patients enrolled for late decompression will be kept in hard collar while in a rehabilitation facility and will undergo research related Computed Tomography (CT) studies at 3 weeks post

admission. If interim imaging studies indicate glacial translation, earlier decompression and internal fixation may be considered. The choice of surgical technique for decompression is standard of treatment at the Shock Trauma Center. Standard surgical decompression of the spinal cord will be by a select group of Department of Neurosurgery staff with full familiarity with cervical spine surgical interventions.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

ASIA Motor score after 3 months.

Secondary outcome measures

1. Functional outcomes will be assessed at 3 and 12 months after injury by the following:
 - 1.1. Functional Independence Measure (FIM)
 - 1.2. Spinal Cord Independence Measure (SCIM)
 - 1.3. Walking Index of Spinal Cord Injury (WISCI)
 - 1.4. Quality of life (Short Form-36)
2. Degree of canal compromise, spinal cord compression and syrinx size, assessed after admission and on pre-operation and post-operation CT and MRI studies of early or late decompression (i.e. after 5 days or after 6 weeks)

Overall study start date

15/04/2007

Completion date

14/04/2009

Eligibility

Key inclusion criteria

1. All adult patients (>17 years old) admitted to University of Maryland Medical System with traumatic central cord syndrome, canal compromise and evidence of spinal cord compression
2. Allen-Ferguson injury classification:
 - 2.1. Distractive Extension Stage 1
 - 2.2. Compressive Extension Stage 1
 - 2.3. Vertical Compression Stage 1
 - 2.4. Compressive Flexion Stage 1
3. Patient with American Spinal Injury Association (ASIA) level of injury from C4 to T1 inclusive
4. Patients with ASIA Impairment Grades B, C, and D/E
5. Pregnant and lactating women are also eligible for the study

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

30

Key exclusion criteria

1. Children aged <18
2. Terminally ill patients, patients with non-survivable injuries and patients with demyelinating disease
3. Patients likely not to be able to appear for follow up
4. Allen-Ferguson Injuries:
 - 4.1. Distractive Extension Stage 2, 3
 - 4.2. Distractive Flexion Stages 1-4
 - 4.3. Compressive Extension Stages 2-4
 - 4.4. Vertical Compression Stages 2-4
 - 4.5. Compressive Flexion Stages 2-4
 - 4.6. Vertical Distraction Injuries
5. Patients with acute disc herniation in need of urgent decompression
6. Patients with progressive neurologic worsening
7. Patients with Spinal Cord Injury WithOut Radiological Abnormality (SCIWORA)
8. Central cord syndrome in association with traumatic brain injury (Glasgow Coma Scale [GCS] <15)
9. Patients with previous cervical spine injury and /or surgery.
10. ASIA (American Spinal Injury Association) grade A patients

Date of first enrolment

15/04/2007

Date of final enrolment

14/04/2009

Locations**Countries of recruitment**

United States of America

Study participating centre

Department of Neurosurgery

Baltimore

United States of America

21201

Sponsor information

Organisation

Maryland Department of Health and Mental Hygiene (USA)

Sponsor details

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Sponsor type

Government

Website

<http://maryland.gov/portal/server.pt?>

ROR

<https://ror.org/02e1t6r96>

Funder(s)**Funder type**

Government

Funder Name

Maryland Department of Health and Mental Hygiene (DHMH). Grant Award Number FHA07-004. (USA)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration