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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

Registration date
06/06/2007

Overall study status
Completed

Last Edited
19/10/2021

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
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
201 W Preston Street
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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