COSMIC: Conservative or early Surgical Management of Incomplete cervical Cord syndrome without spinal instability. Randomized controlled trial

Published: 02-08-2011
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To compare the efficacy of early decompressive surgery to improve functional outcome in patients with cevical incomplete cord lesion without a fracture or instability of the cervical spine compared to those receiving conservative treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON39722

Source
ToetsingOnline

Brief title
COSMIC

Condition

- Spinal cord and nerve root disorders
- Head and neck therapeutic procedures

Synonym
spinal cord lesion

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: subsidie wordt aangevraagd

Intervention

Keyword: incomplete cord lesion, spinal cord, surgery, treatment

Outcome measures

Primary outcome

Primary outcome: functional outcome at two years measured by Dutch translation

of mJOA.

Secondary outcome

Secondary outcomes: motor and sensory scores according to the ASIA standards at

six weeks, 12 weeks, 12 months, stay at a high care department (medium care,

intensive care), stay at the hospital, complication rate, mortality rate, sort

of rehabilitation and kind of rehabilitation, quality of life, and arm/hand

function assessed by the disability of the arm, shoulder and hand questionnaire

(DASH),SCIM III .

Study description

Background summary

Incomplete spinal cord lesion due to a cervical spine trauma is frequently encountered. It may happen without radiological signs of cervical instability. Uncertainty about the treatment still exists. A good recovery has been described after conservative treatment. Conservative treatment was usually considered when a fracture or dislocation of the spine were absent. Incomplete spinal cord lesion is often seen in hyperextension trauma in the elderly with degenerative spondylotic stenotic cervical spine. However, some reports suggest a better outcome after surgical decompression. Randomized trials have not been performed. To avoid discussion about possible confounding or effectmodification

related to the mechanism of trauma, this study will focus on incomplete cord lesion in patients without fracture or instability of the cervical spine on radiological examination.

Study objective

To compare the efficacy of early decompressive surgery to improve functional outcome in patients with cevical incomplete cord lesion without a fracture or instability of the cervical spine compared to those receiving conservative treatment.

Study design

The study has been designed as a multi center, open, randomized controlled trial. Participating centers should have adequate experience with the treatment of patients with spinal cord trauma and neurosurgical facilities should be available on a 24 hours a day basis. All primary analyses will be performed on an intention to treat basis, but if considered useful, additional per protocol analyses will be performed.

Intervention

Conservative treatment or surgical decompression of the spinal cord

Study burden and risks

N/A

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Groote Plein-Zuid 10
Nijmegen 6525 GA
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Groote Plein-Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

all patients with a history of a traumatic event to the cervical spine with an incomplete spinal cord lesion due to a cervical spine trauma. At CT scanning with reconstruction and at MRI signs are not seen that could indicate a fracture of the cervical spine or instability.

Exclusion criteria

ASIA A at neurologic examination,mental impairments, a preexistent neurologic deficit of arms and/or legs, psychiatric illness, significant comorbidity interfering with the indication to perform surgery or not, use of anticoagulating drugs, addiction to drugs or alcohol (more than five units daily), not speaking Dutch language fluently, not willing to participate, participating in another trial

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-01-2014
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO Date:	02-08-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-06-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-09-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL36977.091.11