The value of diffusion-weighted MR imaging and biomarkers in cerebrospinal fluid in acute spinal cord injury as predictors of outcome.

Published: 20-05-2008
Last updated: 10-05-2024

The purpose of the this study is to evaluate the prognostic capabilities of DWI and biomarkers in CSF in patients with SCI.

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

Summary

ID

NL-OMON31829

Source
ToetsingOnline

Brief title
SPinal cord Diagnostic Improvements (SPIDI) study

Condition

- Spinal cord and nerve root disorders

Synonym
spinal cord injury, traumatic myelopathy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Financiering is aangevraagd bij het Int. Fund

for Paraplegiologie (Zurich Zwitserland)

Intervention

Keyword: biomarkers, CSF, MR-DWI, Spinal cord injury

Outcome measures

Primary outcome

1 Size of the lesion (hemorrhage, edema, contusion) in the spinal cord measured in millimetres using MRI

2 Size of the lesion (hemorrhage, edema, contusion) in the spinal cord measured in millimetres using DWI

3 The values of Apparent Diffusion Coefficients (ADC) in the lesion and in normal spinal cord in 10-3 mm2/s measured using DWI

4 The concentrations of Neuron Specific Enolase, Glial Fibrillary Acidic Protein, S-100ß, Neurofilament Protein, Tau and Myelin Basic Protein in CSF in patients with SCI.

5 Evaluation of the ASIA classification system and SCIM of all patients at different times

Secondary outcome

is not applicable

Study description

Background summary

Magnetic Resonance Imaging (MRI) is still the technique of choice for the evaluation of spinal cord injury (SCI). MRI however has limited succes as a prognostic tool.
Diffusion-weighted MRI (DWI) has been proposed as a method to evaluate the

integrity of microstructural changes in the spinal cord. Besides spinal cord imaging there is a method for the assesment of spinal cord injury using biomarkers in cerebrospinal fluid (CSF).

Study objective

The purpose of the this study is to evaluate the prognostic capabilities of DWI and biomarkers in CSF in patients with SCI.

Study design

In this prospective cohort study the data are collected of all patients with SCI. The following descriptive data are collected: mechanism of injury, clinical data and radiological findings using conventional radiographs and computed tomography.
Within 24 hour after the initial trauma all patients with SCI recieve a MRI and a DWI examination.
Within 72 hours after the initial trauma all patients with SCI will be operated on the cervical and/or thoracic spinal cord.
During this operation a 3 ml CSF sample will be taken
Throughout the rehabilitation and during admission the SCIM (Spinal Cord Impairment Measurement) and the ASIA (American Spinal Injury Association) classification system will be evaluated. This will be evaluated until 12 months after the initial trauma.

Study burden and risks

The DWI examination will last 1-2 minutes. During this examination a minimum of one nurse will be present throughout the examination. Hemodynamic unstable patients will be accompanied by an anesthesiologist and/or traumatologist.
The spinal puncture will be performed during the operation. Patients will be completely sedated. Therefore, the burden of this spinal puncture is restricted to a minimum.
It is the opinion of this research group that the possible advantages of DWI and biomarkers for future patients with SCI outweigh the minimal disadvantages of these diagnostic tests.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen

NL
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

closed spinal cord injury
associated neurologic deficit
primarily referred to UMC St. Radboud
Glasgow Coma Scale of 15

Exclusion criteria

penetrating spinal cord injury
normal neurologic examination
ischaemic spinal cord injury
traumatic brain injury
pre-existent neurological disorder

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2008
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL20061.091.07