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

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

Ethical reviewApproved WMOStatusRecruitment stoppedHealth condition typeSpinal cord and nerve root disordersStudy typeObservational 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

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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

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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

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# **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

КП

INL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2008
Enrollment:	10
Туре:	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 CCMO ID NL20061.091.07