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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22830

Source
NTR

Brief title
SPIDI Trial

Health condition

Spinal cord injury, biomarkers, MRI-DWI

Sponsors and support

Primary sponsor: Radboud University Nijmegen Medical Centre
Source(s) of monetary or material Support: International Foundation for research in Paraplegia

Intervention

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

N/A

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

Prospective study determing whether MRI-Diffusion Weighted Imaging (DWI) and biomarkers in CSF have prognostic capabilities in patients with Spinal Cord Injury (SCI).

Study design

- MRI-DWI within 24 hours after the initial trauma

- A CSF sample within 72 hours after the initial trauma

Intervention

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 cerebrospinal fluid (CSF) sample will be taken

Contacts

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Eligibility criteria

Inclusion criteria

1. Closed spinal cord injury

2. Associated neurologic deficit

3. Primarily referred to UMC St. Radboud

4. Glasgow Coma Scale of 15

Exclusion criteria

1. Penetrating spinal cord injury

2. Normal neurologic examination

3. Ischaemic spinal cord injury

4. Traumatic brain injury

5. Pre-existent neurological disorder

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2008
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-07-2008
Application type:	First submission

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
NTR-new	NL1323
NTR-old	NTR1381
Other	UMCN St Radboud : UMCN-2008
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A