MRI of the lumbar and sacral nerve roots in patients with a lumbar discus hernia, a pilot study

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To visualize the affected nerve roots using DTI with tractography. The anatomy and organisation of the nerves on the level of the lumbar disc herniation will be visualized. Diffusion parameters as FA, ADC, AD, and RD could provide valuable...

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

Summary

ID

NL-OMON41345

Source
ToetsingOnline

Brief title
MRI of the nerve roots in hernia patients

Condition

- Spinal cord and nerve root disorders

Synonym
herniated disc, Lumbar disc herniation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diffusion Tensor Imaging, Lumbar disc herniation, Magnetic Resonance Imaging, Nerve roots, Tractography

Outcome measures

Primary outcome

The apparent diffusion coefficient (ADC), fractionele anisotropie (FA), axiale diffusiviteit (AD), and radiale diffusiviteit (RD) will be measured. The program ExploreDTI (©: Alexander Leemans) will be used to visualize these nerves. With this it will be examined whether it is possible to characterize the diffusion of the molecules in the nerve tissue. The ADC, FA, AD, and RD will be measured in the DTI images using the program ExploreDTI of Alexander Leemans, working in the UMCU at the Image Science Institute (ISI). The hypothesis is that the diffusion parameters of the affected nerve root on the level of the lumbar disc herniation will differ from the contralateral nerve root. This will be verified by comparing them to nerve roots in healthy volunteers. This will also indicate whether or not the herniated disc will affect the diffusion parameters and anatomy of other nerve roots in the patient.

Secondary outcome

The secundary research variable is the anatomy and functionality on the level of the lumbar disc herniation and the nerve roots in comparison to the healthy contralateral side. To be able to answer this the research question we would like to visualize the anatomy and organisation of the nerves of this group of patients, where we want to compare the affected nerves and the healthy nerves

qualitatively. Our hypothesis is that the nerves on the level of the lumbar disc herniation will be disturbed. To identify whether or not the hernia does not affect other nerve roots in the patients the results will be compared to the nerve root organisation of healthy volunteers. In case this correlation is identified the information of healthy volunteers will also be used to indicate in what way the hernia affect other nerve roots.

Study description

Background summary

Neurogenic bladder dysfunction (NBD) is common within the peadiatric urology. The exact mechanism which disturbs this innovation of the bladder of these children remains unknown. The anatomical variations have not been described in literature. Diffusion parameters as the fractional anisotropy (FA), Apparent Diffusion Coefficient (ADC), Axiale Diffusivity (AD) and Radiale Diffusivity (RD) could provide information about the functionality of the nerves. Earlier studies have investigated the possibilities of visualizing the periferal nerves using Magnetic Resonance Imaging (MRI) in the combination with Turbo Spin Echo (TSE) and Diffusion Tensor Imaging (DTI) with tractography sequences. Both healthy subjects (protocol number 10/418) as children with spina bifida (protocol number 12-063) have been included. Research where healthy subjects were included showed that it was feasible to visualize the lumbar and sacral plexus using DTI and to measure the diffusion parameters. In the research where spina bifida patients are included the periferal lumbar and sacral nerves were also visualized and the diffusion parameters were measured. However, this group involves many complex cases, through which it is difficult to obtain one overall result whether the nerves are damaged or not. Another complication consists of the broad anatomical variance within this group. Therefore a more simple model has been chosen to indicate the diagnostic value of DTI as a diagnostic technology to visualize the nerve roots and to measure the diffusion parameters of these nerve roots. For this the lumbar disc herniation will be used. Lumbar disc herniation is a medical condition affecting the spine in which a tear in the outer, fibrous ring of an intervertebral disc allows the soft, central portion (nucleus pulposus) to bulge out beyond the damaged outer rings. This is oftend accompanied with intense pain, sciatica. The incidence of sciatica is estimated to be 13-40%.

Study objective

To visualize the affected nerve roots using DTI with tractography. The anatomy and organisation of the nerves on the level of the lumbar disc herniation will be visualized. Diffusion parameters as FA, ADC, AD, and RD could provide valuable information to what extent the nerves are damaged and disfunctional. The contralateral side will be used as a reference. A group of healthy subjects will be included as well. This will provide more insight in the organisation of the nerve roots and will be used to indicate whether or not the herniated disc will affect the diffusion parameters and anatomy of other nerve roots in the patient.

Study design

Cross-sectional study within one University Medical Center. 10 patients suffering from lumbar disc hernation are included. They will be scanned with the MRI in the University Medical Center at the department of Radiology. The MRI images will be examined and will be compared to the contralateral nerve root. Furthermore, 10 healthy volunteers will be included. This will provide more insight in the organisation of the nerve roots and will be used to indicate whether or not the herniated disc will affect the diffusion parameters and anatomy of other nerve roots in the patient.

Study burden and risks

There are no known riscs associated with MRI, other then dizziness, or claustrofobia. The burden of this research is relatively low as there is no need to use a contrast agent. The additional total scan time of this research is 5 minutes. The total scan time of healthy adults is 15 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients
- Patients suffering from lumbar disc herniation
- Symptoms associated with sciatica coming from compressed disfunctional nerves at the level of L3 - S1
- Patients < 60 years;Healthy subjects
- Volunteer must me healthy
- Volunteer must be older than 18 years
- Volunteer must be willing to sign informed consent

Exclusion criteria

Patients
- Patients with pervious history of spinal trauma, surgery or neurological disease
- Patients with previous history of malignancies
- Patients with previous radicular syndrom
- Patients with other back problems
- Patients with a contraindication to MRI (i.e. pacemaker);Healthy subjects
- Volunteers with a contraindication to MRI (i.e. pacemaker)
- Volunteers who do not want to be informed about potential findings related to their health

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	14-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-01-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-05-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-08-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL43311.041.13