MRI of the nerves of the sacral plexus.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27087

Source
NTR

Health condition

Anatomy sacral plexus
Neurogenic bladder

Anatomie sacrale plexus
Neurogene blaas

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Funding of Ministry of OC&W to universities

Intervention

Outcome measures

Primary outcome

1. Image analysis of the visibility of the nerves of the sacral plexus and the pudendal nerve and pelvic nerve on the MRI images obtained with the different parameter settings following a score system;

2. Analysis of the anatomy of the sacral plexus. The branching of the roots will be assessed;

3. Image analysis of the Contrast to Noise Ratio (CNR) on the different MRI images obtained with the different parameter settings. The mean and SD's of the CNR's will be compared witch each other to assess the image quality;

4. Calculation of the apparent diffusion coefficient (ADC) and the fractional anisotropy (FA) to get insight in the nature of the diffusion. This in view of our follow-up study in children.

Secondary outcome

The number of non-analyzable images will be registered.

Study description

Background summary

Background of the study:

The pediatric urologist is often confronted with children suffering from dysfunctioning of the bladder. When this dysfunctioning of the bladder is neurogenic, this is often caused by congenital anomalies as spina bifida, sacral agenesis or other congenital anomalies of the spinal cord or sacrum. The innervation of the bladder in these children is disturbed, and causes problems with the storage of urine or emptying of the bladder. Long-term bladder dysfunctioning can lead to severe deterioration of the bladder and upper urinary tract function. The hypothesis of this study is that there exist variations of the sacral plexus that lead to the complicated incontinence in children with spinal or sacral congenital anomalies. More insight in the disturbed innervation of the bladder in these children is necessary for better understanding and a better treatment of these congenital anomalies. This can result in improved quality of life of these children. MRI of the sacral plexus and its branching nerves, that are responsible for innervation of the bladder, is a challenge. This is because of the close anatomical relationship of the nerves and surrounding tissues, like muscles and veins, which have similar relaxation times as the nerves. With diffusion-weighted imaging these problems can be overcome and the peripheral nerves can be visualized over long trajectories. First results are promising, but optimization of the parameter settings is necessary. By applying DWI acquisitions in multiple directions, the random movement of water molecules can be measured. In nerves this movement of water molecules is directed along the fibers, which makes fiber tracking possible. This so called diffusion tensor imaging (DTI) is also an appropriate sequence for visualizing the nerves of the sacral plexus. However, the spatial resolution of DWI and DTI is low. Recently, 3D isotropic sequences are developed, with a voxelsize down to 0.5 mm3 at 3.0 T and an acceptable acquisition time. A multi-echo data image combination (MEDIC) sequence will be used. This gradient-echo (GE) sequence uses muliple echoes for multiple aqcuisitions. This leads to a high signal to noise ratio in the same acquisition time. Also 3D turbo spin echo (TSE) with variable flip angles is such a new 3D sequence. TSE is used a lot in daily clinical routine, but TSE at higher field strengths is limited to the specific absorption rate (SAR). By first bringing the protons in a pseudo steady state,

high signal intensities can be acquired with the variable flip angles for the whole k-space filling. High signal intensities are obtained, while the SAR can be reduced with 70%. For optimization of the MRI sequences we choose to set up a subject study in healthy adult volunteers, before we want to depict the sacral plexus of the children with it.

Objective of the study:

The aim of this research is to study the MRI-sequence with the best parameter settings for the most optimal image quality to visualize the sacral plexus and its branching nerves. Diffusion-weighted imaging, diffusion tensor imaging, 3D-GE-MEDIC and TSE with variable flip angles will be compared.

Study design:

This will be a unicenter, cross-sectional study (timeschedule: 3 months). 10 volunteers will undergo a MRI-scan in a 3.0 T MRI-scanner. Diffusion-weighted images, diffusion tensor images, 3D-GE-MEDIC images and 3D TSE with variable flip angles images will be made. The MRI-images will be analysed.

Study population:

Healthy male or female volunteers aged 18 years and older.

Primary study parameters/outcome of the study:

1. Image analysis of the visibility of the nerves of the sacral plexus and the pudendal nerve and pelvic nerve on the MRI images obtained with the different parameter settings following a score system;

2. Analysis of the anatomy of the sacral plexus. The branching of the roots will be assessed;

3. Image analysis of the Contrast to Noise Ratio (CNR) on the different MRI images obtained with the different parameter settings. The mean and SD's of the CNR's will be compared witch each other to assess the image quality;

4. Calculation of the apparent diffusion coefficient (ADC) and the fractional anisotropy (FA) to get insight in the nature of the diffusion. This in view of our follow-up study in children.

Study objective

When the optimal MRI protocol for imaging the sacral plexus and its branching nerves is known, the sacral plexus of children having neurogenic bladder dysfunction due to congenital spinal or sacral anomalies can be imaged. Because not much is known about the disturbed innnervation of the bladder in these children. The hypothesis of this study is that there exist variations of the sacral plexus that lead to the complicated incontinence in children with spinal or sacral congenital anomalies.

Study design

After acquisition of the images, the quality will be assessed using a score table. The branching of the nerves will also be assessed following a score table. CNR will be calculated on a Philips workstation. ADC and FA values will be calculated with the program ExploreDTI (www.exploredti.com).

Intervention

Diagnostic MRI images with the following sequences:

1. Diffusion weighted imaging (DWI);

2. Diffusion tensor imaging (DTI);

3. Multi-echo data image combination (MEDIC);

4. Turbo spin echo (TSE) with variable flip angles.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male or female volunteers;

2. Age: 18 years and older;

3. The participant must willingly give written informed consent prior to the start of the study.

Exclusion criteria

1. Volunteers who underwent surgery in the past related to the lumbosacral spine or pelvis;

2. Volunteers with urologic problems in the past wherefor treated by the (pediatric) urologist;

3. Volunteers with a general contraindication for MRI (including cardiovascular pacemakers, claustrofobia);

4. Volunteers with a BMI (body mass index) of < 18,5 or a BMI of >25 kg/m2. A BMI between 18,5 and 25 kg/m2 is classified as 'normal weight' . BMI is calculated following the equation BMI = mass (kg)/ length^2 (cm);

5. Volunteers who don't want to be informed about incidentally discovered lesions;

6. Employees of the Departments of Pediatric Urology and Radiology of the UMC Utrecht.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2011
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-02-2011
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	NL2653
NTR-old	NTR2781
Other	Protocol number UMC Utrecht : 10-418
ISRCTN	ISRCTN wordt niet meer aangevraagd.g

Study results

Summary results
N/A