Optimization of the MRI protocol for imaging the sacral plexus and its branching nerves

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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...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and peripartum neurological conditions
Study type	Observational non invasive

Summary

ID

NL-OMON36634

Source
ToetsingOnline

Brief title
MRI of the sacral plexus

Condition

- Congenital and peripartum neurological conditions

Synonym
disfunctioning of the bladder, Neurogenic bladder

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 3D isotropic imaging, Diffusion weighted imaging, Neurogenic bladder, Sacral plexus

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

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.

Study objective

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 burden and risks

Every volunteer will undergo 1 MRI-scan. The MRI-scan will last approximately 55 minutes, with the volunteer lying still. The MRI-scan is completely non-invasive, no contrast agent is necessary and it is without any side-effects.

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

- male or female volunteers
- age: 18 years and older
- the participant must willingly give written informed consent prior to the start of the study

Exclusion criteria

- volunteers who underwent surgery in the past related to the lumbosacral spine or pelvis.
- volunteers with urologic problems in the past wherefor treated by the (pediatric) urologist
- volunteers with a general contraindication for MRI (including cardiovascular pacemakers, claustrofobia)
- volunteers with a BMI (body mass index) of < 18,5 or a BMI of >25 kg/m2. This is because fat can lead to distortion on the MRI images. 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).
-volunteers who don't want to be informed about incidentally discovered lesions
-employees of the Departments of Pediatric Urology and Radiology of the UMC Utrecht

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-03-2011
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	23-02-2011
Application type:	First submission
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	NL34530.041.10