MRI study of the thoracic spine anatomy and possible applications in regional anaesthesia

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30322

Source
ToetsingOnline

Brief title
MRI of thoracic spine

Condition

- Other condition

Synonym
nvt

Health condition

onderzoek naar anatomische kennis van het ruggenmerg tov de thorakle wervelkolom

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Anaesthesia, Anatomy, Imaging, MRI

Outcome measures

Primary outcome

The main study parameter is distance between anatomical structures, as

previously alluded. The variable component will be imaging orientation (to

estimate introduced error of previous study), and patient orientation

(laterally decubitus or sitting)

Secondary outcome

nvt

Study description

Background summary

Regional anaesthesia is often desirable due to lower drug toxicities, quicker recovery times, and, most importantly, greater patient safety. The experimental delivery of spinal anaesthetics at thoracic level, above the cauda equina, has been shown to be potentially very valuable.
It is, however, not evident from literature the relative movement of the spinal cord to the encompassing dural layer for different patient postures; which may determine the success of anaesthetic delivery. We intend an imaging study of volunteers to determine the modal anatomical positions of the spinal cord, dura and other relevant structures in a clinically relevant posture, namely, laterally decubitus.
Our previous research has shown that the spinal cord lies more ventral at thoracic levels in volunteers lying supine. However, the quantitative quality of the data could be improved with different slices and automated segmentation techniques. In addition to investigating anatomical position of the structures in laterally decubitus volunteers, we will revisit the measurements of the

first study to determine the error introduced by taking medial sagittal slices, and hand segmentation of the respective structures. By this we hope to draw more quantitative results on anatomical position.
The underlying goal of the research is to develop thoracic combined Spinal-Epidural (CSE) techniques, including optimal patient positioning (specific goal of MRI research). Yet to be submitted research indicates that there is significant room for delivery of intrathecal anaesthetic above the termination of the cord.

Study objective

The primary objective is to state the modal anatomical position of the spinal cord within the surrounding thecal tissue for volunteers lying laterally recumbent, with MRI imaging perpendicular to the line of the of the spinal canal. We hypothesize that the cord lies more ventral at middle thoracic height, than at lower and high thoracic levels.

Study design

The study is an observational imaging study, employing magnetic resonance imaging (MRI)

Study burden and risks

For the participants, there are negligible risks associated with the study. The volunteers for the study will be required to lie laterally recumbent in the MRI scanner; which is somewhat inconvenient. The authors have previously done this, and it is not dangerous. Further, there are no significant health risks posed by the MRI scanner itself.

Contacts

Public
TU Delft

Michelangelolaan 2
5623NL, Eindhoven
Nederland
Scientific
TU Delft

Michelangelolaan 2
5623NL, Eindhoven
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy subjects, 18-60 years of age

Exclusion criteria

Diseases of the spinal canal, such as tumour or metastases

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2007
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO Date:	01-02-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL15639.060.06