Subjective neurosurgical evaluation of cervical spine synthetic *BoneMRI* CTs generated with convolutional neural networks.

Published: 22-04-2021
Last updated: 30-01-2025

The primary aim of this pilot study is to evaluate whether adding BoneMRI to the current workflow, which consists of a standard MRI scan and only on indication an X-ray or CT scan, improves the neurosurgeon satisfaction and certainty in the surgery…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone disorders (excl congenital and fractures)
Study type	Observational non invasive

Summary

ID

NL-OMON49245

Source
ToetsingOnline

Brief title
BoneMRI in Neurosurgical workflow

Condition

- Bone disorders (excl congenital and fractures)
- Spinal cord and nerve root disorders

Synonym
Cervical radiculopathy, neck hernia

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: afdeling Radiologie Isala en MRIGuidance BV Utrecht (aanbieder BoneMRI),MRIGuidance BV, Utrecht (aanbieder BoneMRI).

Intervention

Keyword: BoneMRI, Cervical spine, Neursurgery, Synthetic CT

Outcome measures

Primary outcome

The primary outcome is the satisfaction and certainty of the neurosurgeon in the surgery planning measured with a 10-point Likert scale before viewing the BoneMRI preoperative, after viewing the BoneMRI preoperative and postoperative. Comparison of Likert-scores of part A (T0) of the questionnaire to part B (T1) and part A (T0) to part C (T2) will be performed. For the questions of part B and C only pertaining to the BoneMRI, the median or mean Likert scores of each question, depending on normality of the data, is evaluated.

Secondary outcome

The secondary outcome is the diagnostic accuracy of BoneMRI in visualization of pathoanatomic aspects related to radiculopathy compared to the current workflow (MRI, X-ray and CT scan if available) as assessed by the neurosurgeon with perioperative findings serving as reference standard.

Study description

Background summary

Magnetic Resonance Imaging (MRI) is frequently used in the evaluation of symptoms referring to diseases of the cervical spine, such as radiculopathy and

myelopathy. MRI offers excellent soft-tissue visualization without the use of ionizing radiation. CT can be very useful as an adjunct to MRI to assess osseous involvement of disease. International literature has not yet reached consensus about the best diagnostic strategy in osseous conditions of the cervical spine. Recently, Bone MRI was developed, a quantitative MRI technique by MRIGuidance BV©, which is based on a multiple gradient-echo sequence and a machine learning processing pipeline and is capable of generating CT-like quantitative bone MRI images. The use of Bone MRI is currently investigated in multiple musculoskeletal studies. If successful, future patients can benefit from better diagnostic techniques, without the potential hazards of ionizing radiation.

Study objective

The primary aim of this pilot study is to evaluate whether adding BoneMRI to the current workflow, which consists of a standard MRI scan and only on indication an X-ray or CT scan, improves the neurosurgeon satisfaction and certainty in the surgery planning compared to the current workflow without BoneMRI in patients with cervical radiculopathy and/or -myelopathy eligible for surgery.

Study design

This study is a prospective longitudinal, single center, clinical pilot study.
All patients with cervical radiculopathy and/or myelopathy referred to the neurosurgery department of the Isala hospital in Zwolle, the Netherlands, who are on the waiting list for cervical spine surgery and that gave informed consent on participation in this study. The patients will undergo an extra MRI prior to admission. This extra MRI is viewed by the neurosurgeon, who will complete a questionnaire.

Study burden and risks

The patient does not benefit from participating in this study and will receive routine care. For research purposes an additional MRI scan of the cervical spine will be obtained for each patient. Patients are not exposed to ionizing radiation and do not make an additional hospital visit. The surgery will be performed according to the conventional protocols and imaging, without the BoneMRI.
Thus the burden exists of being present in the hospital 2 hours prior to the admission, of which 4 minutes lying still for for the scan.
This study may contribute to a lower radiation dose in future patients: if Bone MRI images are sufficient for assessing osseous structures of the cervical spine, an additional CT scan will become redundant.

Contacts

Public
Isala Klinieken

Dr. van Heesweg 2
Zwolle 8025 AB
NL
Scientific
Isala Klinieken

Dr. van Heesweg 2
Zwolle 8025 AB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patients with the clinical diagnosis of cervical radiculopathy and/or myelopathy;
• Received a MRI cervical spine;
• Eligible for cervical spine surgery based on neurosurgical evaluation of the clinical symptoms and imaging.

Exclusion criteria

• History of osteosynthesis in the spine
• Previous participation in the study;

• Malignancy.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-07-2021
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	22-04-2021
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO

Date:	22-04-2021
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL74463.075.20