# Reconstructing CT images from MRI scans of the cervical spine: a feasibility and validation study of Bone MRI

Published: 09-04-2018
Last updated: 12-04-2024

The objective of this study is to investigate whether Bone MRI can be used for the 3D visualization and characterization of bone.

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

## Summary

### ID

NL-OMON46499

**Source**
ToetsingOnline

**Brief title**
CSI: Bone MRI

### Condition

- Bone disorders (excl congenital and fractures)

**Synonym**
bone disease, radiculopathy

**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:** cervical spine, CT, MRI, radiation dose reduction

## Outcome measures

### Primary outcome

Objective and subjective image quality of Bone MRI will be investigated.

Geometrical accuracy and voxelwise similarity will be assessed to evaluate

objective image quality and will be leading in the acceptance of Bone MRI

images.

### Secondary outcome

Subjective image scores is our secondary outcome measure. Bone MRI scans will

be assessed by two radiologists and one neurosurgeon and should reach a score

of 3 or higher (scale 1-4) in 80% in order to be qualified as acceptable, in

the rating of predetermined anatomical structures.

# 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. 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 MRI Guidance 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 objective of this study is to investigate whether Bone MRI can be used for the 3D visualization and characterization of bone.

**Study design**

This study is a prospective single-centre feasibility and validation study. Patients referred to the Radiology Department for a MRI scan of the cervical spine, will be asked to participate in this study. After written informed consent is obtained, patients will receive an extra MRI sequence in addition to the standard MRI scan and an additional CT of the cervical spine.

**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 sequence and CT scan of the cervical spine will be obtained for each patient. Patients are exposed to a low amount of ionizing radiation (1 mSv); this is nearly 40% of the yearly natural background radiation dose and low compared to other computed tomography studies. 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

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

- Subjects * 50 years old
- Indication for MRI cervical spine
- Eligible for MRI
- Written informed consent
- Able to read in Dutch

## Exclusion criteria

- Not eligible for MRI
- Previous participation in the study
- Pregnancy
- Concomitant participation in a research project in which the patient is exposed to ionizing radiation
- History of osteosynthesis of the cervical spine
- History of (psychiatric) disorder which causes the patient to be incompetent to make a thought-out decision.

# Study design

## Design

**Study type:** Observational non invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-04-2018 |

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| Enrollment: | 50 |
| Type: | Anticipated |

## Ethics review

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| Approved WMO Date: | 09-04-2018 |
| 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 | NL65041.075.18 |