

# Clinical validation of BoneMRI in the spine

No registrations found.

|                              |                  |
|------------------------------|------------------|
| <b>Ethical review</b>        | Positive opinion |
| <b>Status</b>                | Recruiting       |
| <b>Health condition type</b> | -                |
| <b>Study type</b>            | -                |

## Summary

### ID

NL-OMON28518

### Source

NTR

### Brief title

BoneMRI\_CIP005

### Health condition

Symptoms related to a spine disorder with suspected underlying involvement of osseous structures

## Sponsors and support

**Primary sponsor:** MRGuidance

**Source(s) of monetary or material Support:** Industry

## Intervention

## Outcome measures

### Primary outcome

Geometric accuracy in terms of visualization of the 3D osseous morphology of the spinal column.

### Secondary outcome

Investigate the applicability of BoneMRI in specific applications for the spine.

## Study description

### Background summary

BoneMRI is a quantitative 3D MRI technique that has been developed recently by MRIGuidance BV©, which is based on a multiple gradient-echo sequence and a machine learning processing pipeline. The BoneMRI technology is capable of generating CT-like, quantitative radiodensity bone MRI images to visualize cortical and trabecular bone, allowing to assess bone structure and morphology, in addition to regular clinical MRI images. The use of BoneMRI has been investigated and clinically validated in multiple musculoskeletal studies involving the cervical spine, hip and sacro-iliac joint. In order to clinically use BoneMRI in the entire spine, the BoneMRI technology needs to be validated in that area as well, focussing on geometrical and voxelwise accuracy of the radiodensity contrast to assure accurate visualization of the osseous structures. As robustness against expected data variability between hospitals is crucial for successful machine learning algorithms, multiple MR field strengths and scanner types from different manufacturers will be included in this study. If successful, BoneMRI will facilitate a better, easier and cheaper workflow by enabling diagnosis, treatment planning and surgical navigation using a single radiological examination, without the potential hazards of ionizing radiation. This study is a prospective multi-center clinical validation study, following a comparative design.

### Study objective

The BoneMRI technology is accurate in visualization of the osseous structures

### Study design

After 1 year of inclusion the primary outcome will be assessed via an equivalency design. During this equivalency design the surface distance between the cortical edge of osseous structures as determined on a bone MRI and on a CT scan will be compared. The secondary endpoint will also be assessed after 1 year of inclusion via a survey that will be sent out to all of the end users of BoneMRI

## Intervention

NA

## Contacts

### Public

MRGuidance B.V.  
Fleur ten Tije

0854000810

### Scientific

MRGuidance B.V.  
Fleur ten Tije

0854000810

## Eligibility criteria

### Inclusion criteria

Subjects  $\geq 18$  years old  
Indication for diagnostic MRI of the spine  
Indication for diagnostic CT of the spine  
Eligible for MRI  
Eligible for CT  
Written informed consent

### Exclusion criteria

Pregnancy  
History of (psychiatric) disorder which causes the patient to be incompetent to make a thought-out decision  
claustrophobia  
>3 months between CT and MRI scan

## Study design

### Design

Intervention model: Other  
Allocation: Non controlled trial  
**Control:** N/A , unknown

### Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 01-06-2021  
Enrollment: 450  
Type: Anticipated

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion  
Date: 15-06-2021  
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

NTR-new

Other

### ID

NL9570

METc UMCU : METC-20-801/D

## Study results