Clinical validation of BoneMRI in the spine

Gepubliceerd: 15-06-2021 Laatst bijgewerkt: 18-08-2022

The BoneMRI technology is accurate in visualization of the osseous structures

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON28518

Bron
NTR

Verkorte titel
BoneMRI_CIP005

Aandoening

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

Ondersteuning

Primaire sponsor: MRIguidance
Overige ondersteuning: Industry

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

The BoneMRI technology is accurate in visualization of the osseous structures

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

NA

Contactpersonen

Publiek

MRIguidance B.V.
Fleur ten Tije

0854000810

Wetenschappelijk

MRIguidance B.V.
Fleur ten Tije

0854000810

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subjects ≥ 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2021
Aantal proefpersonen:	450
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-06-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9570
Ander register	METc UMCU : METC-20-801/D

Resultaten