High-field MRI of the inner ear in sensorineural hearing loss

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22903

Source
Nationaal Trial Register

Brief title
7T MRI in SNHL

Health condition

sensorineural hearing loss

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: not appilcable

Intervention

Outcome measures

Primary outcome

image quality and diagnostic value

Secondary outcome

na

Study description

Background summary

Over the last decades treatment options for sensorineural hearing loss (SNHL) have greatly improved thanks to new insights into pathophysiology and development of new technologies, e.g. radiosurgery or implantable electronic devices. Due to such advancements there is a growing interest in very detailed evaluation of the inner ear and central auditory pathway in vivo. Such detailed information can be obtained with ultra high field MRI. Yet, the technical complexity accompanying higher magnetic field strengths and the particular anatomic configuration of the temporal bone with many air-bone-fluid interfaces giving cause to artifacts, make 7T imaging of the inner ear and retrocochlear structures demanding. Previously we've shown that 7T imaging of the inner ear is feasible, but further improvement and/or extension of the scan protocol is required to meet the needs for therapy planning and therapy monitoring in hearing loss.
This study is a prospective observational study to develop and improve new and existing MR sequences for inner ear imaging at 7T and to investigate the clinical added value of 7T imaging (in comparison to 3T imaging)

Study objective

Image quality on 7T outperforms lower field MRI for patient care and/or clinical research.

Study design

Participants of this study will undergo medium field MRI (1.5T or 3T) as part of their clinical work-up and an additional 7T MRI
Diagnostic value will be evaluated in comparison to other available imaging studies and/or preoperative findings and/or performance outcome and/or anatomical studies and/or literature values.

Contacts

Public
LUMC
Berit Verbist

0715264376
Scientific
LUMC
Berit Verbist

0715264376

Eligibility criteria

Inclusion criteria

- be able and willing of giving informed consent
- age 12-99 years
- clinical indication for MR imaging of the temporal bone and/or auditory pathway

Exclusion criteria

- contra-indication to MRI exposure, including cardiac pacemaker and implants not approved for ultra-high field MRI (see www.mrsafety.com), pearcings or other metal objects attached to the body that cannot be removed
- claustrophobia

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-12-2015
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	20-12-2019
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	ID
NTR-new	NL8247
Other	METC LUMC : P15.132

Study results