7T MRI of the inner ear and central auditory pathway in sensorineural hearing loss

Published: 02-09-2015
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1. to develop and improve new and existing MR sequences for inner ear imaging at 7T2. to investigate the clinical added value of 7T imaging (in comparison to 3T imaging)

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Ear and labyrinthine disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON50425

Source
ToetsingOnline

Brief title
7T MRI in SNHL

Condition

- Ear and labyrinthine disorders congenital
- Hearing disorders

Synonym
deafness, hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 7T, hearing loss, high field MRI, inner ear

Outcome measures

Primary outcome

The primary end-points of this study are 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.

Study objective

1. to develop and improve new and existing MR sequences for inner ear imaging at 7T
2. to investigate the clinical added value of 7T imaging (in comparison to 3T imaging)

Study design

Prospective observational.
Development of MRI sequences and improvements in acquisition parameters or pulse sequences will be guided and monitored during quality review meetings

with physicists and radiologist(s). Image quality will be evaluated in a comparative study between the standard clinical protocol performed on 1,5 or 3T and the developed 7T sequences to investigate whether the image quality on 7T outperforms lower field MRI for patient care and/or clinical research. The diagnostic value will be evaluated in comparison to other available imaging studies and/or peroperative findings and/or performance outcome (eg audiogram, speech perception) and/or anatomical studies and/or literature values.

Study burden and risks

Participants of this study will undergo a 7T MRI scan additional to a medium-field MRI (1,5T or 3T MRI), which is performed as part of their clinical work-up. The duration of the 7T MR session will be scheduled for 1 hour. Additional findings thanks to higher resolution on 7T MRI may be beneficial for the patient in terms of higher diagnostic yield with potential improvement in the therapeutic strategy. No risks are anticipated for the subjects in the study population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

eligible for MRI examination for evaluation of hearing loss

Exclusion criteria

contra-indications for MRI

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):	17-12-2015
Enrollment:	151
Type:	Actual

Ethics review

Approved WMO

Date:	02-09-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-11-2020
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL53145.058.15