Visualization of Endolymphatic HydRops: Techniques of ImaGing Optimization

Published: 07-11-2019
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To develop a robust MR imaging protocol applicable in the diagnostic workup and follow up of suspected MD patients.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Hearing disorders
Study type	Observational invasive

Summary

ID

NL-OMON48126

Source
ToetsingOnline

Brief title
VERTIGO

Condition

- Hearing disorders

Synonym
Vertigo and hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: HagaZiekenhuis
Source(s) of monetary or material Support: Nederlandse Vereniging voor Radiologie

Intervention

Keyword: Hydrops, Ménière, MRI, Vertigo

Outcome measures

Primary outcome

The difference in proportion of eligible patients that has developed a clinical

diagnosis of MD after 2 year follow-up, between EH and non-EH group.

Secondary outcome

The difference in the severity of EH before and after treatment in clinical

definite MD patients.

Study description

Background summary

Ménière*s disease (MD) is an inner ear disorder characterized by recurrent self-limiting attacks of vertigo associated with fluctuating sensorineural hearing loss, tinnitus, and aural fullness. Although the pathophysiology of MD remains unclear, it is universally agreed that the pathogenesis includes development of endolymphatic hydrops (EH). The diagnosis of MD currently relies solely on clinical criteria. Unfortunately, distinguishing MD from other vertigo-associated inner ear disorders is complicated by lack of a specific diagnostic test and a high degree of clinical heterogeneity, especially in early stages of the disease. Recently, 3T MR imaging after delayed IV Gadolinium showed promising results in visualizing EH in vivo using 3D IR and 3D FLAIR techniques. However, the value and exact clinical application in MD has not yet been validated. Moreover, all studies on the visualization of EH so far have involved clinically well-defined patients with MD. The diagnostic value of EH in patients with vertigo of unclear origin is uncertain. Treatment for MD differs from other inner ear disorders, thereby emphasizing the importance of accurate and early diagnosis. To date, no studies are available which specifically address imaging derived parameters in therapeutic evaluation strategies. The visualization of EH, using delayed IV Gd-enhanced 3D FLAIR MRI, may aid clinicians in diagnosing MD and monitor treatment effects.

Study objective

To develop a robust MR imaging protocol applicable in the diagnostic workup and follow up of suspected MD patients.

Study design

The present study is a prospective cohort study that will be carried out in the Haga Teaching Hospital in The Hague.

Study burden and risks

Most patients included in this study will undergo standard of care MR imaging, except for post-treatment imaging of the patients undergoing IT dexamethasone and EDB. Investigational MRI requires a new IV contrast bolus. Gadolinium-based contrast media have a very low risk of allergic-like reactions. MRI up to 8T is considered a non-significant risk by the FDA and ICNIRP. No significant risks are expected.

There are no direct benefits for the patients participating in this study, although evaluation of endolymphatic hydrops may help to start relevant treatment in an early phase of the disease. Nevertheless, their participation will contribute to a better understanding of the value of MRI in patients with MD. Moreover, an imaging-based substrate for Meniere disease in vivo does help patients and their environment in the acceptance and acknowledgement of the disease.

Contacts

Public
HagaZiekenhuis

Els Borst-Eilersplein 275
Den Haag 2545 AA
NL
Scientific
HagaZiekenhuis

Els Borst-Eilersplein 275
Den Haag 2545 AA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

18 years or older
Legally capable
Written informed consent
Clinically diagnosed with definite Ménière, probable Ménière or other vertigo-associated inner ear pathology by an ENT specialist according to the AAO-HNS criteria

Exclusion criteria

<18 years old
Inability to provide written consent
Gadolinium allergy
Claustrofobia
Implanted non-MRI compatible device or material (e.g. intracranial aneurysm clip, non-MRI compatible devices, materials or metals, etc.)
Pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	263
Type:	Anticipated

Ethics review

Approved WMO Date:	07-11-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL69723.058.19