Clinical evaluation of ocular MRI for ophthalmic conditions

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The primary objective of this pilot study is to determine the clinical value of ocular MRI for patients with the following ocular conditions:- Glaucoma treated with a Baerveldt implant- Visual field loss- Diplopia

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON45951

Source
ToetsingOnline

Brief title
Evaluation of Ocular MRI

Condition

- Other condition
- Glaucoma and ocular hypertension

Synonym
glaucoma, high eye pressure

Health condition

oogaandoeningen, klachten van het zicht

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: afdelingsfonds

Intervention

Keyword: MRI, Ophthalmology, Radiology

Outcome measures

Primary outcome

For group 1:

A) The dimensions of the Bleb of the Baerveldt implant after implantation.

For group 2:

A) The presence of an abnormal signal intensity on the optic nerve.

For group 3:

A) Location of the eye relative to the extra ocular muscles.

B) Change in therapy after additional MRI-imaging.

Secondary outcome

For group 1:

A) Location of the Bleb with respect to the extra ocular muscles.

B) Dimensions of the Bleb as measured at the 3Tesla MRI exam

For group 2:

A) Thickness of the optic nerve

For group 3:

N/a

Study description

Background summary

MRI is a technique that uses a magnetic field and radio waves to image the inner part of the human body. It is a patent friendly, non-invasive and harmless technique. Over the past decadence, MRI has shown to be useful in the diagnosis and treatment of diseases, in biomedical research and in fundamental research on the human body.

The sensitivity of MRI to eye-motion, however, has prevented its regular use in ophthalmology. Recently, a variety of new MRI-techniques has been developed, allowing the use of MRI for the imaging of the eye and its surrounding tissues.

Study objective

The primary objective of this pilot study is to determine the clinical value of ocular MRI for patients with the following ocular conditions:
- Glaucoma treated with a Baerveldt implant
- Visual field loss
- Diplopia

Study design

This study will be a multicenter, non-blinded observational study of patients with various ocular conditions. These patients will receive an 7Tesla ocular MRI-scan. Eight patients of group 1 (see 'Study population') will also receive an 3Tesla ocular MRI-scan. All MRI-scans will be performed at the Leiden University Medical Center.

All patients of group 1 (see 'Study population') will furthermore undergo several ocular motility measurements in the Rotterdam Eye Hospital.

Study burden and risks

The study consist of one, or in some cases two, ocular MRI-scans, with a maximum duration of one hour each. When the obtaining informed consent and similar actions are taken into account, the subjects are requested to be present for 1,5 hours, or 2,5 hours in the case of two MRI-scans.

All patients of group 1 (see 'Study population') will furthermore undergo several ocular motility measurements in the Rotterdam Eye Hospital. This will take at most 1 hour.

The only risks in this study are the risks related to the magnetic field that is present at the MRI-scanner. By screening the subject for contraindications for MRI-scanning, this risk is effectively eliminated.

Therefore, the burden associated is low and the risks are negligible

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The inclusion critria are:

1. One of the specified ocular conditions (see K2 - study population)
2. Age > 18 years
3. Gender: both male and female
4. Written informed consent

Exclusion criteria

The exclusion critria are:
1. Contraindications to (Ophthalmic) MRI scanning, including:
a. Claustrophobia
b. Pregnancy
c. Pacemakers and defibrillators
d. Nerve stimulators
e. Intracranial clips
f. Metallic fragments
g. Cochlear implants
h. Ferromagnetic implants
i. Hydrocephalus pump
j. Permanent make-up
k. Tattoos above the shoulders
l. Piercings (unless they can be taken out)
m. Subjects who cannot keep their head still (e.g. Tremor, Parkinson*s disease)
n. Severe physical restriction (e.g. completely wheelchair dependent);In the case of uncertainty about the MRI-contraindications, the MR-safety commission of the radiology department will decide whether this subject can be included in the study or not.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-12-2018

Enrollment:	87
Type:	Actual

Ethics review

Approved WMO Date:	05-11-2018
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	NL65633.058.18

Study results

Date completed:	31-08-2020
Actual enrolment:	30