Assessment of the value of Magnetic Resonance Imaging in diagnosis and treatment planning for Uveal Melanoma

Published: 11-05-2017
Last updated: 16-04-2024

With this study we aim to improve the current ocular MRI protocols and assess its additional value in the diagnosis and therapy planning of UM.1. Extend the current 7T MRI protocols to provide information to differentiate tumour types.2. Translate...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Ocular neoplasms
Study type	Observational invasive

Summary

ID

NL-OMON47770

Source
ToetsingOnline

Brief title
MRI for Uveal Melanoma

Condition

- Ocular neoplasms
- Ocular neoplasms

Synonym
eye tumor, uveal melanoma

Research involving
Human

Sponsors and support

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

voor Blinden en Slechtzienden

Intervention

Keyword: MRI, Ophthalmology, Ultrasound, Uveal Melanoma

Outcome measures

Primary outcome

The primary endpoints of this study are the MRI-based description of the tumour and the comparison with the conventional ultrasound description:

1. Tumour prominence

2. Tumour basal diameter

3. The presence of extrascleral extension

4. Ciliary body involvement of the tumour

5. Radiological characteristics of UM, including signal level after contrast, on diffusion and perfusion.

7T MRI will be used as gold standard for tumour dimensions. Histological material will be used as gold standard for extrascleral extension, ciliary body involvement and for correlating radiological characteristics with the pathology. The 3T MRI findings will be compared to the 7T MRI findings to assess whether the increased resolution of the 7Tesla is needed for the evaluation of UM or whether they can also be performed with the images from a clinical 3Tesla scanner.

Secondary outcome

As secondary endpoints we will evaluate whether there are MRI findings with prognostic implications and the role of MRI in the follow-up of patients

treated with ruthenium plaque therapy.

Study description

Background summary

Uveal melanoma (UM) is the most common malignant primary tumour of the eye in the adult.
The Leiden University Medical Center (LUMC) is the National Expertise Center for the diagnosis and treatment of UM in the Netherlands, with about 200 patients per year being referred.
The decision between an eye preserving therapy and enucleation (removal of the eye) is primarily based on the tumor dimensions and location. At the moment 2D Ultrasound (US) is the standard exam performed for this evaluation. However, Magnetic Resonance Imaging (MRI), given its high spatial resolution, 3D imaging capabilities and high intrinsic contrast provides important additional clinical information. In LUMC a 7T MRI has been performed in 10 patients as ophthalmologists had doubts about the accuracy of the 2D ultrasound measurements of these patients. The high-resolution 3D MRI images of the eye, changed in 2 patients the treatment plan, making them still eligible for eye-preserving therapy, whereas according to the US measurements they would need to be enucleated.

Study objective

With this study we aim to improve the current ocular MRI protocols and assess its additional value in the diagnosis and therapy planning of UM.
1. Extend the current 7T MRI protocols to provide information to differentiate tumour types.
2. Translate these protocols to the clinical 3T MRI.
3. Assess the added value of 3D MR-images from 3T MRI and 7T MRI on measuring the tumour dimensions when compared to 2D US.
4. Assess the added value of 3T MRI and 7T MRI to evaluate extrascleral extension of the tumour, compared to the clinical US evaluation.
5. To evaluate whether MRI can non-invasively classify different types of UM.
6. To assess the added value of MRI in the evaluation of tumour response to ruthenium plaque brachytheraphy and proton therapy treatment.

Study design

The study is a single center cross-sectional study to evaluate the value of MRI in the characterization of UM. The study will consist of four different groups of a total of 130 patients, one for MRI protocol development, one for the comparison with conventional US, one to compare image characteristics on MRI

with histologic characterization in enucleated eyes and the other one to assess the value of a follow-up MRI to evaluate treatment response in patients treated with ruthenium plaque therapy.
The subjects will undergo a MRI scan protocol both at 3T and/or 7T MRI scanner. These data will be compared with the standard clinical evaluations, such as US, and for the patients whose eye will be enucleated, with histological material.

Study burden and risks

Fourty subjects will undergo two MRI scan protocols (at a 3T and 7T MRI scanner) on two different days. Thirty patients will undergo four MRI scan protocols (either 3 or 7T) at 1, 3, 6, 12 months after treatment and sixty patients will undergo one 3T MRI scan.
The MRI protocol includes the use of a gadolinium based contrast agent and each takes less than 60 minutes.
The risks are the ones associated with MRI and with the injection of a gadolinium-contrast agent. Safety is evaluated by carefully questioning each subject for MRI contraindications and by checking the renal function to keep the risk associated with participation at minimal.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. UM diagnosed at the LUMC
2. Age > 18 years
3. Gender: both male and female
4. Written informed consent

Exclusion criteria

1. Contra-indication to MRI scanning:
a. Claustrophobia
b. Pregnancy
c. Pacemakers and defibrillators
d. Nerve stimulators
e. Intracranial clips
f. Intraorbital or intraocular 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 (eg. Tremor, Parkinson*s disease)
n. Severe physical restriction (completely wheelchair dependent)
o. 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.
2. Contra indication for gadolinium such as renal insufficiency or contrast allergy.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-11-2017
Enrollment:	130
Type:	Actual

Medical products/devices used

Generic name:	MRI
Registration:	No

Ethics review

Approved WMO

Date:	11-05-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	04-07-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	11-07-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	18-09-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	18-11-2019
Application type:	Amendment
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	NL57130.058.16