MRI for brachytherapy of Uveal Melanoma patients

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1. Assess the effect of Ru-106 brachytherapy applicators on tumor dimensions. 2. Assess the value of DWI and PWI as an early predictor of therapy response after Ru-106 brachytherapy in UM.

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

Summary

ID

NL-OMON51655

Source
ToetsingOnline

Brief title
MRI for brachytherapy in Uveal Melanoma

Condition

- 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: KWF

Intervention

Keyword: Brachytherapy, MRI, Ultrasound, Uveal Melanoma

Outcome measures

Primary outcome

1. Tumor dimensions: Prominence, largest basal diameter, second basal diameter.

2. Changes in tumor dimensions, volume between the different time points.

3. Tumor apparent diffusion coefficient (ADC), time-intensity curve (TIC),

pharmacokinetic parameters (Ktrans, Ve, Vp).

Secondary outcome

Additional changes in the radiological appearance of the UM on MRI, such as:

• Signal on T1 and T2 (measured relative to the choroid and eye muscle

respectively)

• Homogeneity of the lesion

• Presence of retinal detachment

• Localization compared to FAF

Study description

Background summary

Brachytherapy is the optimal treatment modality for small to medium sized uveal melanoma (UM), which is the most common primary malignant intra-ocular tumor in adults. Conventionally, 2D Ultrasound (US) is used to plan the brachytherapy, e.g. the tumor height determines the treatment duration, and for follow-up, e.g. a decrease in tumor height. In recent years, we have introduced MR-Imaging as a new and valuable imaging modality for UM, as it can provide 3D volumetric and functional data of the tumor, which can potentially improve the therapy planning and follow-up.

Currently, the time during which the brachytherapy applicator is attached to

the eye, is based on the pretreatment tumor height. It is, however, not known if the suturing of the applicator results in a deformation of the eye and or tumor, which could result in an over- or underdosage of the tumor. Moreover, functional MRI techniques, such as diffusion weighted imaging (DWI) and perfusion weighted imaging (PWI), have been proposed as an early marker of therapy response, but have not been systematically evaluated.

Study objective

1. Assess the effect of Ru-106 brachytherapy applicators on tumor dimensions.
2. Assess the value of DWI and PWI as an early predictor of therapy response after Ru-106 brachytherapy in UM.

Study design

The study is a single-center prospective study. All participants will undergo an MRI scan before, during and 3 and 6 months after Ru-106 brachytherapy.

The patients will receive 3Tesla MRI scans using a dedicated UM protocol which is also used clinically for patients who receive proton beam therapy. The protocol contains anatomical scans, used to assess the tumor dimensions, and functional scans. The MRI data will be compared to the conventional ophthalmic imaging data, in particular Ultrasound imaging, as well as, Fundus Autofluorescence (FAF).

Study burden and risks

This study has no invasive procedures. Subjects with contraindications for MRI will be excluded. There are no known risks associated with MRI and the presence of brachytherapy applicators in-situ. Participants have no direct personal benefit from participating in this study. However, the study results may contribute to the improved treatment planning and/or follow-up of brachytherapy in future UM patients.

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

1. Diagnosis of primary UM
2. UM lesions arising from the choroid or ciliary body
3. No history of previous UM treatments
4. UM patients who will be treated with brachytherapy
5. Tumor prominence >3 mm

Exclusion criteria

1. Subjects who are not legally capable
2. Subjects under the age of 18
3. Contraindications to MRI scanning, including:
o Claustrophobia
o Pregnancy
o Pacemakers and defibrillators
o Nerve stimulators
o Intracranial clips
o Metallic fragments
o Cochlear implants
o Ferromagnetic implants
o Hydrocephalus pump
o Permanent make-up
o Tattoos above the shoulders
o Subjects who cannot keep their head still (eg. Tremor, Parkinson*s disease)

o Severe physical restriction (eg. 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 or not.
4. 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:	Recruitment stopped
Start date (anticipated):	25-11-2022
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	3Tesla MRI
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	24-07-2022
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	NL81227.058.22

Study results

Date completed: 04-01-2024

Summary results
Trial ended prematurely