# Optical Imaging for the follow-up of Uveal Melanoma patients

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Primary objective1. Assess that FAF can visualize the irradiated retina effects at an early stage after Ru-106 brachytherapy and PBT. Secondary objective1. Assess if these FAF-images can be correlated to the treatment plan.2. Correlate the observed…

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Ocular neoplasms |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON57016

**Source**
ToetsingOnline

**Brief title**
Optical Imaging for Uveal Melanoma patients

### Condition

- Ocular neoplasms

**Synonym**
eye melanoma, 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, Ocular Oncology, Optical Imaging, Proton beam therapy

## Outcome measures

### Primary outcome

Main study parameters/endpoints:

For Ru-106 brachytherapy and PBT treated patients between each timepoint:

Primary objective:

• Location of FAF changes

• Characteristic FAF changes (mottling pattern and rim of increased FAF).

### Secondary outcome

Secondary objectives:

• For brachytherapy, the diameter of the FAF changes compared to the dimensions

of the used applicator.

• For PBT, distances of retina with FAF changes to the clip locations.

• Relation of FAF changes to abnormalities seen on OCT and funduscopic imaging

both at the same timepoint and at later timepoints.

# Study description

### Background summary

Uveal melanoma (UM) is the most common primary malignant intra-ocular tumour in adults. Eye preserving treatments such as Ru-106 brachytherapy and proton beam therapy are offered to the majority of patients. After treatment, a reduction in tumour thickness on ultrasound is the primary indicator of treatment response, but it can take up to a year to become apparent. Although both treatments have a high, >95%, rate of local control, the treatment also induces damage to the healthy retina surrounding the tumour, which threatens the patient*s vision. A recent study showed that Fundus Autofluorescence (FAF) can

accurately visualize this radiation-induced damage within 6 months after brachytherapy. We hypothesize that FAF could be a valuable instrument to further improve the treatment, as it provides a means to directly link the planned target volume to the actually treated volume. This recent proof-of-principle study was however limited, as it only included brachytherapy patients and did not include data on the treatment planning or other imaging data post treatment.

### Study objective

Primary objective
1. Assess that FAF can visualize the irradiated retina effects at an early stage after Ru-106 brachytherapy and PBT.

Secondary objective
1. Assess if these FAF-images can be correlated to the treatment plan.
2. Correlate the observed changes on FAF-imaging with conventional ophthalmic imaging (fundoscopy and OCT).

### Study design

This study is a single centre prospective study design. All participants will undergo optical imaging examinations before, 3- and 6 months after either Ru-106 brachytherapy or proton beam therapy.

The patients will receive additional imaging exams consisting of: fundoscopic imaging, FAF and Optical Coherence Tomography (OCT).

### Study burden and risks

This study has no invasive procedures. 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 future brachytherapy and proton beam therapy treated UM patients.

## Contacts

**Public**
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL
**Scientific**

Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333ZA
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

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

## Inclusion criteria

- Diagnosis of primary uveal melanoma
- No history of previous uveal melanoma treatments
- No diagnosis of other retinal diseases
- Uveal melanoma patients who will be treated with either brachytherapy or proton beam therapy

## Exclusion criteria

- Subjects who are not legally capable
- Subjects under the age of 18

# Study design

## Design

**Study type:** Observational non invasive
Masking: Open (masking not used)

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| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 15-09-2024 |
| Enrollment: | 30 |
| Type: | Anticipated |

### Medical products/devices used

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|---|---|
| Registration: | No |

## Ethics review

Approved WMO

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|---|---|
| Date: | 25-09-2024 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>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 | NL86790.058.24 |