New Treatment Options for Metastatic Uveal Melanoma

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

Summary

ID

NL-OMON46156

Source
ToetsingOnline

Brief title
UM-MetColl

Condition

- Ocular neoplasms
- 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: Europese Unie Horizon 2020 Grant #: 667787

Intervention

Keyword: Melanoma, Metastases, Treatment, Uveal

Outcome measures

Primary outcome

Genetic, molecular and immunologic characteristics of primary tumor, metastases

and peripheral blood of patients diagnosed with uveal melanoma.

Analysis of molecular and immunologic experimental therapies in in vitro and in

vivo models.

Secondary outcome

not applicable

Study description

Background summary

In recent years, improvements have been made in the local control of primary uveal melanoma (UM) and treatment modalities have been developed which allow preservation of the eye. However, despite these developments, there is still no effective treatment for UM metastases.
The aim of this study is to facilitate the development of new treatment options for metastasized UM. By analyzing a large collection of UM metastases and corresponding primary UM and blood samples, genetic, molecular and immunologic characteristics will be revealed as potential treatment targets. Moreover, the usage of in vitro and in vivo models based on primary UM and metastasis tissue will allow the evaluation of treatment efficacy.
In order to apply future therapies effectively, cases with a small tumor load are more likely to respond well than cases with large tumors. One can imagine that early detection of metastases will benefit the patient. It would be useful to have properly validated bloodmarkers of metastasis, however, these still have to be developed. Therefore, we will evaluate the sensitivity and specificity of existing markers and try to identify new markers of metastasis.

Study objective

The objectives of the study are the following:

- To develop a treatment for uveal melanoma metastases. For this purpose, the following will be conducted:

* To establish an European Biobank of (preferably matched) UM metastasis, primary tumor and blood samples
* To analyze molecular characteristics of UM metastasis and corresponding primary UM
* To characterize and evaluate anti-tumor activity of T cells in primary tumors, metastases and blood of UM patients
* To establish in vitro and in vivo models for preclinical analysis
* To identify markers of metastasis in the patient*s blood

Study design

International multicentre observational study.
Primary tumor tissue and blood will be obtained from patients diagnosed with primary uveal melanoma. Patients with a high risk of developing metastases will be asked to give blood every 6 months (for analysis of biomarkers of metastases). Metastatic tissue will be obtained (by biopsy or resection) from patients suspected of or diagnosed with metastases.

Study burden and risks

The analyses in primary UM will be done on tumor tissue that is obtained by enucleation or biopsy and which remained after diagnostic or prognostic examination. This involves no additional burden to the patient. Patients with metastases will be asked for a biopsy for research purposes, besides a biopsy for diagnostic purposes. This is associated mainly with small risks of pain, bleeding, local infection.
Peripheral blood will be obtained by venipuncture. There are minimal risks associated with venipuncture. Participating in this study may be beneficial to patients who will be followed every six months to give blood, as frequent contact with physicians may lead to early identification of emerging metastases. The molecular and cellular analyses, in vitro and in vivo, will not have direct benefits for the involved patients. The outcomes of this study may contribute to the future treatment of 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

I-1. Patients must be *18 years of age.
I-3. Patients with either primary UM completing I-4 to I-6 inclusion criteria or with lesions highly suspected of metastases from uveal melanoma and completing I-7 to I-10 inclusion criteria.
I-4. Patients presenting an untreated primary UM diagnosed by local investigator and at a high risk of developing metastatic disease.
I-5. Patients undergoing a fine-needle biopsy aspiration for diagnosis procedure or an enucleation for therapeutic procedure in the setting of its care.
I-6. Tumour tissue should be obtained before any local radiation therapy or systemic treatment.
I-7. Patients presenting lesions highly suspected of metastases from uveal melanoma. Histological confirmation of uveal melanoma metastasis is mandatory and may be done by a local pathologist after inclusion in the study. If the suspected lesions are not uveal melanoma metastases after histological analysis the patient will not be eligible for follow-up analysis.
I-8. Patients undergoing a diagnostic procedure for histological confirmation of metastasis (for instance percutaneous fine needle biopsy, partial hepatectomy etc.) in the setting of routine care. Patients considered by their clinicians, because of any medical condition, at high-risk of procedure complication linked to study sampling should not be included.
I-9. Tumor tissue should be obtained before any systemic treatment for metastatic disease.
I-10. Metastatic patients will be included even if they have had previous surgeries for

metastatic UM.

Exclusion criteria

E-1. Patients presenting a melanoma arising from another tissue than choroid (e.g. conjunctiva, skin, mucosa etc.).
E-2. Patients with other malignancy within the last 5 years except: adequately treated non-melanoma skin cancer, curatively treated in situ cancer of the cervix, ductal carcinoma in situ. Patients with a history of localized malignancy diagnosed over 5 years ago may be eligible provided they completed their adjuvant systemic therapy prior to randomization and that the patient remains free of recurrent or metastatic disease.
E-3. Previous systemic treatment for metastatic UM.
E-4. Patients not consenting to tissue or clinical data collection for research purpose
E-5. Patients known to suffer from HIV, active tuberculosis, active hepatitis C, B or other active viral hepatitis.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-02-2018
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	19-06-2017
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	NL57166.058.16