Optical coherence tomography and widefield fundus photography for 3D radiation- dose response relationship in partial eye irradiation

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To gain insight into the incidence of retinopathy and optic neuropathy in relation to the radiation dose in order to develop a normal tissue complication probability (NTCP) model for the eye and the optic tract.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON52706

Source
ToetsingOnline

Brief title
iOCT

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders
- Miscellaneous and site unspecified neoplasms benign

Synonym
radiation retinopathy, retinal damage after radiation therapy, retinal vasculopathy after radiation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: oncology, prediction algorithm, radiotherapy, retinopathy

Outcome measures

Primary outcome

Main study parameters/endpoints:

- Determine retinopathy and optic neuropathy and translate this to ocular damage map

- Develop irradiation dosimetry map of the eye / optic tract

- Combine both maps to determine prediction model and NTCP

Secondary outcome

- possible other side effects of the eye and/or optic tract caused by irradiation of malignancies arising in the brain, head and neck such as; dry eye, cataract , and scleral necrosis.

- the impact on QoL of ocular complications caused by irradiation of the eye and/or optic tract

- the influence of concurrent parameters such as hypertension, diabetes mellitus, smoking (previous and history), alcohol intake, dyslipidemia, family history of cardiovascular disease, personal history of cardiovascular disease, cardiovascular risk estimation for the following 10-years (based on the Framingham Coronary Heart Disease Risk Score) on the development of radiation induced retinopathy and optic neuropathy

Study description

Background summary

Radiotherapy (RT) is a mainstay treatment for a variety of intracranial, head and neck tumors such as; sinusoidal tumors, nasopharyngeal tumor, orbital rhabdomyosarcoma and meningioma*s. Due to the complex anatomical relationship it is inevitable to prevent irradiation of healthy tissues surrounding the mentioned tumors. Irradiation of these tumors often involves the eye and optic tract which can induce various ocular complications, including radiation induced dry eye, cataract, secondary glaucoma from neovascularization of the iris, scleral necrosis, retinopathy and optic neuropathy. Radiation retinopathy and optic neuropathy are the two most visually significant complications of radiotherapy. With the advent of new irradiation technologies such as; Intensity Modulated Radiotherapy (IMRT), Volumetric Arc Therapy (VMAT), proton therapy, and the Magnetic Resonance Linear accelerator (MR-Linac), precise dose distributions conform the target are realizable. Considering this, it is likely that irradiation of the eye and/or the optic tract can be lessened. Furthermore, the dose-response relationship for irradiation of parts of the eye and the optic tract is not well established so it is not known where and to what extent to decrease the dose. Gaining more insight in to radiation induced retinopathy and optic neuropathy is needed to develop a prediction model in order to minimize irradiation of the optic tract while performing radiotherapy for sinusoidal tumors, nasopharyngeal rhabdomyosarcoma or meningioma*s. With the new possibilities of modern radiation techniques now more than ever correct prediction of side effects are needed.

Study objective

To gain insight into the incidence of retinopathy and optic neuropathy in relation to the radiation dose in order to develop a normal tissue complication probability (NTCP) model for the eye and the optic tract.

Study design

Prospective multicenter self-controlled study design in which the eye and optic tract of the not irradiated side is the control for the irradiated side.

Study burden and risks

Barring some minor discomfort to the subjects no severe risk is expected as a result of this study. First, after administration of fluorescein 100mg/ml solution patients can experience minor transitory complaints such as; vomiting, nausea, dizziness, and headache. In rare cases minor allergic reactions can occur including; itching of the skin, redness, and urticaria. In exceptional

cases (1 in 10 000) an anaphylactic reaction can occur. Second, mydriasis is provided by topical mydriastic eye drops, including topical tropicamide 0.5% and/or phenylephrine 5%. These drops can temporarily lead to local irritation of the eyes or blurred vision. Therefore, patients are advised not to drive a car during the first 4 hours after examination.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all the following criteria:
- >18 years of age
- Underwent external beam radiation therapy (EBRT) for sinusoidal tumors, nasopharyngeal tumor, orbital rhabdomyosarcoma, uveal melanoma or meningioma for >= 2 years

- Signed informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Any ocular disease / abnormality that prevents good quality imaging of the retina.
- Any ocular disease / abnormality that presents asymmetrically (affecting one eye more than the other e.g., anisometropia) that could influence the outcome measurements and is not related to radiation.
- Other medical conditions which enables patients to participate the study e.g. psychologically not able to participate or undergoing palliative treatment.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-09-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	22-09-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	11-03-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	30-08-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Not approved Date:	23-11-2022
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	NL71040.058.20