Late effects of radiotherapy in patients with optic nerve sheath meningioma

Published: 10-05-2012
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Assessment of late effects of radiotherapy in patients with ONSM.

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

Summary

ID

NL-OMON37447

Source
ToetsingOnline

Brief title
Late effects of RT in ONSM

Condition

- Ocular neoplasms
- Ocular neoplasms
- Nervous system neoplasms benign

Synonym
optic nerve meningioma, orbital tumor

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: late effects, meningioma, optic nerve sheath meningioma, radiotherapy

Outcome measures

Primary outcome

Side effect of radiotherapy:

1. visual deterioration

2. painful eye, dry eye, retinal damage, pituitary function loss

Secondary outcome

3. Preservation or improvement of visual acuity,

4. Health related quality of life

Study description

Background summary

Optic nerve sheath meningioma (ONSM) is a rare, slow-growing tumor of the anterior visual pathway and accounts for 1-2% of all meningiomas (The Netherlands ~500 new cases per year of whom 5-10 with ONSM). Although the histological nature of this neoplasm is benign, it causes progressive visual loss and may ultimately lead to blindness if untreated. High precision radiotherapy is now the treatment of choice, because it is impossible to resect the tumor without causing irreversible damage to the optic nerve resulting in blindness. However, little is known about the late effects of the radiotherapy either physical (dry eye, painful eye, retina damage with visual loss, loss of pituitary function) as well as the effect on QoL.

Study objective

Assessment of late effects of radiotherapy in patients with ONSM.

Study design

Observational retrospective study.

Study burden and risks

Burden:

- Standard ophtalmological examnination by an ophtalmologist (non-invasive)
- Fluorescein-angiography of the retinal vessles (intravenous fluorescein 5 ml)
- Blood sample (20 ml)
- Questionnaire (25 multiple choice and open questions)
- Medical history and interview

Total investigation time: 2 hours

Risk:

- Allergic reaction to intravenous fluorescein (rare event <1%)

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Patients after radiotherapy for ONSM, age >18 yrs

Exclusion criteria

pregnant or breast feeding patients

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2012
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO

Date:	10-05-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL39633.018.12