24 year survival in low-grade glioma patients

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The primary study objectives are: (1) to determine the impact of glioma and its treatment on the neurocognitive functioning, health-related quality of life, and mental functioning of LGG patients; and (2) to determine the impact of the disease and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nervous system neoplasms malignant and unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON43414

Source ToetsingOnline

Brief title 24 YEAR LGG SURVIVORS

Condition

• Nervous system neoplasms malignant and unspecified NEC

Synonym low-grade glioma

Research involving Human

Sponsors and support

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

Intervention

Keyword: long-term survival, low-grade glioma, neurocognitive functioning, quality of life

Outcome measures

Primary outcome

Neurocognitive functioning in six cognitive domains (attention, executive

functioning, verbal memory, working memory, psychomotor functioning, and

information processing speed); Health-related quality of life.

Secondary outcome

Radiological outcome; Molecular tumor characteristics in long-term survivors;

Radiological determinants of neurocognitive functioning and health-related

quality of life. Develop new, liquid biopsy based, algorithms to separate long

term survivors from short/median term survivors.

Study description

Background summary

Our previous research among 65 long-term, 12 year survivors of low-grade glioma (LGG) shows that patients who did not have radiotherapy had stable radiological and cognitive status. By contrast, LGG patients who received radiotherapy showed a progressive decline in attentional functioning, even those who received fraction doses that are regarded as safe (*2 Gy). These cognitive deficits are associated with radiological abnormalities. Our results suggest that the risk of long-term cognitive and radiological compromise that is associated with radiotherapy should be considered when treatment is planned. We have identified 46 patients out of the previously mentioned 65 patients who are still alive at an average of 24 years.

Study objective

The primary study objectives are: (1) to determine the impact of glioma and its treatment on the neurocognitive functioning, health-related quality of life, and mental functioning of LGG patients; and (2) to determine the impact of the

disease and its treatment on the quality of life of the informal caregivers of these patients.

Secondary objectives are to identify clinical parameters and patient characteristics/host-related factors in long-term survivors, by using liquid biopsies identify molecular tumor characteristics in long-term survivors, and to evaluate therapy-related and radiology-related parameters as potential determinants of neurocognitive functioning and health-related quality of life.

Study design

The study will employ a cross-sectional study of LGG survivors and their informal caregivers.

Study burden and risks

Considering the median survival of LGG patients of about 7 years, patients surviving over 24 years are extremely rare. Regarding to patient counseling and treatment, it is not only of importance to know the determinants of the clinical status of these patients, but also to discern the biological determinants of long-term survivorship. Related to the venipuncture the patient may feel slight pain or a sting when the needle is inserted. The patient may also feel some throbbing at the site after the blood is drawn. In some cases the venipuncture may give rise to transient hematoma. Since apart from the venipuncture the procedure is identical to the 2 previous assessments in which these patients and informal caregivers participated, they know what to expect. There are no other risks or benefits for the patients or informal caregivers.

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

Histological diagnosis of low-grade glioma (i.e. astrocytomas, oligodendrogliomas, or oligoastrocytomas).

Exclusion criteria

- patient is unable to communicate adequately
- patient has severe limitations in motor functioning

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):	01-03-2017

Enrollment:	92
Туре:	Actual

Ethics review

Approved WMODate:25-11-2016Application type:First submissionReview 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 CCMO

ID NL56604.029.16