Analysis of physical, cognitive, and psychosocial factors of Fatigue in Glioma patients

Published: 18-02-2016
Last updated: 19-04-2024

To describe the cognitive, physical and psychosocial factors of fatigue which may affect fatigue in patients with glioma.

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

Summary

ID

NL-OMON45971

Source
ToetsingOnline

Brief title
AFIG

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumor, glioma

Research involving
Human

Sponsors and support

Primary sponsor: Rijndam revalidatiecentrum
Source(s) of monetary or material Support: Stichting Coolsingel;Rijndam revalidatiecentrum

Intervention

Keyword: Cognitive functioning, Fatigue, Glioma, Physical fitness

Outcome measures

Primary outcome

To describe the physical, cognitive and psychosocial factors of fatigue which can be of influence on the fatigue in patients with glioma. The nature of the experienced fatigue will be described based on the results of the subscales of the MFI. The physical status will be described based on a maximum test (physical fitness) and based on the ambulatory movement registration (physical activity). The cognitive status of the patient will be described based on the neuropsychological examination distinguishing between the domains of attention, memory and executive functioning. The psycho-social status of the patient will be described on based on the results of the questionnaires, focusing on the mood, sleep quality and quality of life.

Secondary outcome

nvt

Study description

Background summary

Gliomas are the most common primary brain tumors. They arise from the glial tissue of the central nervous system and are classified and graded according to the criteria of the World Health Organization. Low-grade gliomas have an average incidence of 1 per 100.000 persons per year. The peak incidence is in the young adult age, between 30 and 40 years old. The survival rate of patients with LGG is increasing due to improved neurosurgical techniques, advanced radiotherapy and chemotherapy. Median survival rates are currently between five and fifteen years. Due to increased life expectancy, new issues in this patient

group arise including daily functioning and social participation.

In 2016 a new WHO classification was issued. This new WHO classification 2016, had an important addition to the WHO classification of 2007, namely the use of molecular parameters to determine tumor entities.
Survival of patients with glioma has increased over recent decades, through the development of new and improved treatment options consisting of neurosurgery, radiotherapeutic and chemotherapeutic interventions. Survival is currently between five and fifteen years.
Recent scientific research shows that the difference in survival between Grade II and Grade III IDH mutated tumors is less different than in the classical histopathological classification. This is especially true for the grade 3 oligodendrogliomas with the molecular entity IDH mutant. The median survival rate is 12-14 years, and thus comparable to the median survival of the LGG tumors as described above.

Patients with glioma report various symptoms due to their disease and/or treatment, such as fatigue, cognitive impairment and mood disorders. These complaints may interfere with the level of functioning and social participation.
Fatigue is the symptom with the greatest impact on quality of life and daily functioning of patients and their relatives.
Cancer-related fatigue is defined as a persistent, (subjectively) sensation of physical, emotional and/or cognitive fatigue or exhaustion related to cancer or the treatment of cancer, which is disproportionate to recent activity and interferes with normal daily functioning. The underlying pathophysiology and mechanisms of this fatigue are so far unresolved. The aetiology of cancer-related fatigue seems multifactorial. There is a lack of understanding regarding the problems of cancer-related fatigue, which makes it difficult to achieve adequate treatment.

It can be concluded that there is a lack of knowledge about the pathophysiology of fatigue in patients with glioma. This research aims is focused on a better understanding of the physical, cognitive and emotional factors of fatigue which can affect the fatigue in patients with gliomas.

Study objective

To describe the cognitive, physical and psychosocial factors of fatigue which may affect fatigue in patients with glioma.

Study design

The study design includes an observational cross-sectional study of patients with glioma.

Study burden and risks

The total investment in time regarding of the patient is 135 minutes per patient and consists of; the completion of the questionnaires, participating in the neuropsychological examination, the execution of the maximal test and receiving instructions with regard to the ambulatory movement registration. During the 5-day ambulatory movement registration, the patient can perform all daily activities. Therefore, no time investment expressed in minutes is mentioned.

All patients will be assessed by the physician, before proceeding to the execution of the maximal exercise test. In addition, an continuous ECG monitoring takes place during the exercises. These actions minimalized the risk of cardiac ischemia and/or arrhythmia at the time of the maximal exercise time.

Filling in the questionnaires, the neuropsychological examination and undergo the physical tests may be perceived as tiresome. To minimize any inconvenience, it was decided that the questionnaires can be completed at home. Also the neuropsychological research is conducted at home, taking into account the load capacity. In addition, the physical tests are clustered in one day part. The blood sampling may give a short-term pain sensation and may possibly give a small bruise

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

Patient population
Diagnosis: confirmed IDH mutated glioma II or III
Time: time post diagnosis >6 months * 5 years
Age: 18 years old or older

Exclusion criteria

Patient population
Treatment: patients receiving <3 months ago any form of cancer-related treatment like a surgical operation, radiotherapy and / or chemotherapy.
Diagnosis: patients with other progressive neurological disease(s and / or a psychiatric diagnosis according to the DSM IV
Diagnosis: patients with history of cardiopulmonary problems which constitute a contraindication for performing a ergometry (VO2max) test.
Language: insufficient comprehension of the Dutch language

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):	27-05-2016
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	18-02-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-07-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-11-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL54616.078.15