"Quality of life of patients with high grade glioma: The development of the PDQ-HC screening list for the need for psychosocial care."

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

Summary

ID

NL-OMON31598

Source ToetsingOnline

Brief title Quality of life of patients with high grade glioma

Condition

• Nervous system neoplasms malignant and unspecified NEC

Synonym

high grade glioma; brain tumor

Research involving Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis

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Source(s) of monetary or material Support: St. Elisabeth ziekenhuis; Universiteit van Tilburg

Intervention

Keyword: High grade glioma, Quality of life, Screening list

Outcome measures

Primary outcome

Quality of life

Secondary outcome

Not applicable

Study description

Background summary

Patients with high grade glioma experience psychosocial problems, which reduce quality of life. There is no screening instrument available for this group to register this uniformly in practice. Therefore, referring to the proper health care worker for psychosocial problems remains difficult. With this study, we aim to determine the psychosocial determinants of quality of life of patients with high grade glioma. Based on this, we hope to develop a screening instrument which can map the need for care. This instrument may include a decision diagram, suited for the individual needs of the patient.

Study objective

This research aims to improve quality of life of patients with high grade glioma. Psychological variables which determine quality of life in this group will be determined. By means of collecting data on several questionnaires about concerns of this group a screening instrument may be developed, named the PDQ-HC (Head cancer), analogous to the PDQ-BC. Apart from generic questions, there is attention for disease specific questions distinguishing the PDC-HC from the PDQ-BC. Aim of this screening instrument is making an inventory of psychosocial problems in a uniform and early manner, making a specific referral possible. Specific psychosocial complaints can be signalled faster in a structured manner, and can be reduced where possible. In this way, patients and family need not be in a disproportionate emotional crisis for more time than necessary.

Study design

prospective follow up study

Study burden and risks

Around diagnosis the MMSE will be administered to patients. This will take approximately 15 minutes. Also, patiens and partners will be asked to fill in some questionnaires around diagnosis, and 3, 6, 12, 18, and 24 months later. This takes approximately 1 hour each time. If the research project raises any questions, patients can contact GM Nefs, neuropsychologist i.o, and R. Van Helvert, nursing specialist neuro-oncology.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years)

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Elderly (65 years and older)

Inclusion criteria

Age of 18 yrs. or older; mastery (speaking, reading, writing) of the Dutch language

Exclusion criteria

Cognitive deterioration (MMSE < 25), insufficient knowledge of the Dutch language, psychiatric illness.

Study design

Design

Study type: Observational non invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Health services research	

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	28-01-2008
Enrollment:	200
Туре:	Actual

Medical products/devices used

Registration:

No

Ethics review

Approved WMO	
Date:	15-01-2008
Application type:	First submission

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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 NL20035.008.07