Evaluation of the Neurologic Assessment in Neuro-Oncology (NANO) criteria among brain cancer patients

Published: 17-10-2014
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The development of an objective, standardized and validated tool for the assessment of clinical outcome of brain tumor patients

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

Summary

ID

NL-OMON56677

Source
ToetsingOnline

Brief title
Evaluation of the NANO criteria

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumor, glioma

Research involving
Human

Sponsors and support

Primary sponsor: Dana-Farber/Harvard Cancer Center
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: brain tumor, NANO, physical examination, RANO

Outcome measures

Primary outcome

Interobserver variability of the criteria of each neurologic examination domain

specified in the NANO scale

Secondary outcome

none

Study description

Background summary

The evaluation of response and progression in brain tumor patients is mainly based on evaluation with MR imaging. Despite that the physical evaluation has a central role, but as of today an objective and validated scale to assess clinical progression and respons through a standardized physical eximination is lacking. This study will develop such a scale.

Study objective

The development of an objective, standardized and validated tool for the assessment of clinical outcome of brain tumor patients

Study design

220 brain tumor patients will undergo twice on one day by two a neurological examination by two different phycisians and/or specialized nurses. The findings will be recorded on a specially developed form.

Study burden and risks

The burden is minimal, there are no risks.

Contacts

Public
Dana-Farber/Harvard Cancer Center

Brooline Avenue 450
Boston, MA MA 02215
US
Scientific
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US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

suffering from a brain tumor
18 year or older
informed consent

Exclusion criteria

not able to undergo a physical examination

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	17-10-2014
Application type:	First submission
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	NL49229.078.14