# Cognitive functioning and health-related quality of life in long-term anaplastic oligondendroglioma and oligoastrocytoma survivors from the EORTC 26951 study: second follow-up

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Primary objective: To assess NCF, HRQoL, mood, fatigue, cognitive complaints and health care utilization in long-term surviving patients with anaplastic oligondendroglioma and oligoastrocytoma.Secondary objective:To assess cerebral abnormalities in...

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| **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-OMON55406

**Source**
ToetsingOnline

**Brief title**
Follow-up of anaplastic oligondendroglioma and oligoastrocytoma patients

### Condition

- Nervous system neoplasms malignant and unspecified NEC

**Synonym**
oligondendroglioma/oligoastrocytoma, primary brain tumor

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Haaglanden Medisch Centrum
**Source(s) of monetary or material Support:** Het onderzoek wordt uitgevoerd door een onderzoeker die betaald wordt middels een subsidie van European Organisation for Research and Treatment of Cancer (EORTC);voor gerelateerd onderzoek

## Intervention

**Keyword:** cognitive functioning, glioma, primary brain tumor, quality of life

## Outcome measures

### Primary outcome

NCF, HRQoL, mood, fatigue, cognitive complaints and health care utilization.

### Secondary outcome

Cerebral abnormalities: white matter intensities (WMI) and global cerebral

atrophy (GCA) of the latest and earlyer MRI scans.

# Study description

### Background summary

The addition of Procarbazine, Lomustine, and Vincristine (PCV) chemotherapy to radiotherapy (RT) proved to be an effective treatment in terms of progression-free and overall survival for newly diagnosed anaplastic oligondendroglioma patients, particularly those with 1p/19q co-deletion. As survival time increases, patients may experience late effects (i.e. side effects that become apparent months or years after treatment has ended) caused by anti-tumor treatment such as radiotherapy. These late effects, including cognitive dysfunction, may subsequently impair the health-related quality of life (HRQoL) of patients. Hence, if treatments that result in effective tumor control are associated with cognitive impairments and worse HRQoL on the long-term, longer survival may be less meaningful for patients. To date, little is known about long-term HRQoL and neurocognitive functioning (NCF) in patients with anaplastic oligodendrogliomas.

The initial results about the effect of the combination of RT and PCV on HRQoL showed that the addition of PCV resulted in a short-term deterioration of HRQoL (i.e. more nausea and vomiting), with no impact on the longer term. For

cognition, only results are available on the longer term (median 12 years after randomization). Habets et al. showed that 30% of the long-term anaplastic oligodendroglioma or oligoastrocytoma survivors without progression (n=27) had severe cognitive impairments, and 44% mild to moderate impairments. Out of the five patients with progression, three had severe cognitive impairment, one had mild to moderate impairment and one had no impairment. This suggests that glioma patients who respond favourably to first-line treatment might actually be at risk for long-term treatment-related cognitive decline. Continued information on NCF and HRQoL in long-term survivors could inform us further about the late effects of treatment with RT and/or PCV in these patients.

Of the 32 anaplastic oligondendroglioma or oligoastrocytoma patients who were included in the follow-up study by Habets et al., a subgroup is still alive. Therefore, we propose to assess NCF and HRQoL, as well as some other relevant patient-centred outcome measures (mood, fatigue, cognitive complaints, health care utilization) in the long-term survivors of the EORTC 26951 study as a second follow-up. Because patient-reported outcome measures may be difficult to complete for patients who are incapacitated or have a poor health status, patient-proxy HRQoL assessment will be considered as an acceptable alternative, as the level of agreement between patient*s and proxy*s in assessing the patient*s HRQoL is generally high. Since cognitive deficits in (long-term) surviving glioma patients who underwent radiotherapy have been associated with radiological abnormalities, we will also explore cerebral abnormalities in the long-term survivors of the EORTC 26951 study.

## Study objective

Primary objective:
To assess NCF, HRQoL, mood, fatigue, cognitive complaints and health care utilization in long-term surviving patients with anaplastic oligondendroglioma and oligoastrocytoma.

Secondary objective:
To assess cerebral abnormalities in long-term surviving patients with anaplastic oligondendroglioma and oligoastrocytoma.

## Study design

We will perform an observational cross-sectional measurement of NCF, HRQoL, mood, fatigue, cognitive complaints, health care utilization and cerebral abnormalities in long-term surviving patients with anaplastic oligodendroglioma and oligoastrocytoma who participated in the EORTC 26951 study, and were also included in the follow-up study by Habets et al.

## Study burden and risks

There are no direct benefits for participants in this study. This study will provide new information on the quality of long-term survival in this patient group. Nevertheless, filling in the questionnaires and undergoing the cognitive tests may be tiresome. The participant burden is believed to be minimal, only related to possible fatigue.

## 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

Patients are eligible for participation if they meet the following criteria:
1) They are diagnosed with an anaplastic oligodendroglioma or oligoastrocytoma;
2) They are adults; over 18 years old;
3) They participated in EORTC 26951 study and the first follow-up study;
4) They have signed the informed consent form, or, when unable to decide, their

legal representative signed the informed consent form for their participation and the use of their data., Proxies are eligible for participation if they meet the following criteria:
1) The patient is not deemed able to participate (as judged by the treating physician) due to a poor physical or mental condition;
2) The patient has given consent that the proxy may participate on his behalf;
3) In the situation that the patient is deemed unable to decide, the legal representative of the patient has signed the informed consent form to participate;
4) The proxy has signed the informed consent form stating he/she agrees to participate;
5) They are adults; over 18 years old.

### Exclusion criteria

Patients are not considered eligible for study participation if:
1) They are not eligible for participating in the study according to the treating physician, due to severe physical or mental impairments hampering filling in the questionnaires or undergoing the cognitive tests;
2) They are unable to communicate adequately., Proxies are not considered eligible for study participation if:
1) They are unable to communicate adequately;
2) The patient, or his/her legal representative, has not signed the informed consent form for proxy participation;
3) They proxy him- or herself has not signed his/her own informed consent form.

## Study design

### Design

**Study type:** Observational non invasive

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

### Recruitment

NL

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| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 25-04-2019 |

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| Enrollment: | 19 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 08-02-2019 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

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| Approved WMO Date: | 11-12-2019 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

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| Approved WMO Date: | 02-09-2021 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br>metc-ldd@lumc.nl |

## 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 | NL66541.098.18 |

# Study results

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| Date completed: | 04-12-2020 |
| Actual enrolment: | 12 |