Medium and long term outcomes after modern radiotherapy for IDH mutated glioma

Published: 23-09-2019
Last updated: 28-04-2024

Objectives: • To report treatment outcomes and radiation-induced toxicity from a prospective, multicentre observational cohort of IDHmG patients treated with radiotherapy and chemotherapy,• To intergrate radiotherapeutic dose distributions, imaging...

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

Summary

ID

NL-OMON52769

Source
ToetsingOnline

Brief title
Radiotherapy in IDH mutated Glioma: Evaluation of Late outcomes (RIGEL)

Condition

- Nervous system neoplasms malignant and unspecified NEC

Synonym
Glioma, IDH mutated. Glioma, low grade (WHO 2) and anaplastic (WHO 3)

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: HollandPTC / Varian consortium

Intervention

Keyword: Anaplastic glioma, Astrocytoma, Glioma, Grade 2 glioma, Grade 3 glioma, IDH mutated, Low grade glioma, Oligodendroglioma, Proton beam therapy, Radiotherapy

Outcome measures

Primary outcome

Main study parameters/endpoints:

• Next intervention free survival during follow-up.

• Freedom of neuropsychological decline during follow-up, defined as a

significant decline in performance in one of the following neuropsychological

tests: Hopkins Verbal Learning test, Trail making test, Controlled Oral Word

Association and Dutch Language Interoperative Protocol.

• Toxicity evaluated with CTCAE - 4.03

Secondary outcome

• MRI changes during follow up.

• Quality of life, as measured by QLQ-C30, BN20 and EQ5D.

• Health economics, as measured by the Productivity Cost Questionnaire and

Medical Consumption Questionaire.

Study description

Background summary

Rationale: Standard postoperative treatment of IDH 1/2 mutated glioma, grade 2 and 3 (IDHmG), consists of radiotherapy and chemotherapy. The improving prognosis of these patients leads towards more emphasis on the long-term effects of treatment. Specifically radiotherapy has been implicated in the development of delayed neurocognitive deterioration. The impact of modern radiotherapy techniques, such as proton beam therapy (PT), and chemotherapy on general toxicity, late neurocognitive outcomes and imaging changes is currently

unclear.

Study objective

Objectives:
• To report treatment outcomes and radiation-induced toxicity from a prospective, multicentre observational cohort of IDHmG patients treated with radiotherapy and chemotherapy,
• To intergrate radiotherapeutic dose distributions, imaging changes and neuropsychological outcome in IDHmG.
• To evaluate the Dutch selection criteria for proton therapy applied to IDHmG based on the outcomes collected in this observational study
• To assess the impact of proton and photon therapy on health related quality of life (QoL) and health-related economics (HR-E) in IDHmG patients.

Study design

Study design: Prospective observational cohort study

Study burden and risks

This project is a multicentre, observational cohort of patients having undergone radiotherapy and chemotherapy for IDHmG. The protocol closely follows the local guidelines for clinical follow up. Specific to the study are extra questionnaires and specific imaging acquired during scheduled MRI*s. Routine neuropsychological investigation is standard of care in ErasmusMC, but not in all participating centers. We feel the additional benefit, and burden, of participation in this study to be negligible.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age > 18 years
- Resection (any grade) or biopsy of one of the following: glioma, WHO grade 2 or 3, IDH mutated
- Indication and fit for standard treatment with radiotherapy and chemotherapy
o For WHO grade 2 tumors 50.4 Gy (RBE) in 28 fractions.
o For WHO grade 3 tumors 59.4 Gy (RBE) in 33 fractions.
- Ability to comply with the protocol, including neuropsychological testing and imaging, as judged by the local investigator.
- Ability to understand the requirements of the study and to give written informed consent.
- Written informed consent.

Exclusion criteria

- Any prior cranial radiotherapy.
- Prior or second invasive malignancy, except non-melanoma skin cancer, completely resected cervical or prostate cancer (with PSA of less than or equal to 0.1 ng/mL).
- Extensive white matter disease visible on pre-therapy imaging (Fazekas grade >=2)
- Contra-indication for MR imaging (i.e. metal implants, claustrophobia)
- Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule in the participating hospitals
- Any other serious medical condition that could interfere with follow-up.
- Aphasia or language barrier interfering with endpoints and questionnaires

(i.e. assessment of QoL, neurocognitive performance)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-12-2019
Enrollment:	79
Type:	Actual

Ethics review

Approved WMO Date:	23-09-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-04-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-02-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	08-11-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	02-04-2024
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
ClinicalTrials.gov	NCT04304300
CCMO	NL69780.078.19