A phase III Prospective Externally Controlled Non-Inferiority Cohort Trial to Compare the Efficacy of Re-Irradiation Schedules in Glioma (RISinG)

Published: 07-04-2020
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To determine if re-irradiation in 4 fractions is non-inferior to 10 fractions in the primary endpoint of survival after re-irradiation. Secondary objectives are to establish and compare health related quality of life (HRQoL), recurrence patterns,...

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

Summary

ID

NL-OMON52643

Source
ToetsingOnline

Brief title
RISinG study

Condition

- Nervous system neoplasms malignant and unspecified NEC
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Synonym
recurrent brain tumor, recurrent high grade glioma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Hypofractionated radiotherapy, Quality of Life, Recurrent glioma, &bullet

Outcome measures

Primary outcome

The primary endpoint is overall survival after re-irradiation.

Secondary outcome

The key secondary endpoint is HRQoL. Other secondary endpoints are recurrence

patterns, progression free survival, toxicity and anti-edema treatment.

Study description

Background summary

Re-irradiation is a generally accepted method for salvage treatment in patients with recurrent glioma. However, no standard radiation regimen has been defined. Hypofractionation with dose-escalation will reduce patient*s burden while maintaining the survival benefit.

Study objective

To determine if re-irradiation in 4 fractions is non-inferior to 10 fractions in the primary endpoint of survival after re-irradiation. Secondary objectives are to establish and compare health related quality of life (HRQoL), recurrence patterns, progression free survival, toxicity and anti-edema treatment.

Study design

Phase II, multi-center clincial trial, including a retrospective control group

Intervention

The entire group will receive 4 stereotactic fractions of radiotherapy. The

historical control group received 10 fractions with a similar biologically equivalent dose.

Study burden and risks

For the patients included in the study, no individual benefits and no known risks are associated with the tests performed. To reduce patients* burden, hospital visits are mainly limited to standard follow-up. Most additional follow-up assessments will be performed by telephone or by self-administered forms. We use the EQ-5D-5L at baseline and 2, 4 and 6 weeks after start of radiotherapy and thereafter the QLQ-C15-PAL to assess HRQoL. The questionnaires could be conducted in less than 10 minutes at home. Additionally, at the same time points patients will be asked about adverse events, anti-edema treatment and reminded to complete their HRQoL assessments during a phone call of a few minutes. Furthermore, technical data, including MRI, CT and radiation treatment plans, acquired in standard care will be utilized.

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

• Supratentorial recurrent high-grade glioma with contrast enhancement on CE-T1
• The gold standard is histological evidence of a recurrence. When a surgical procedure to acquire this evidence is not desirable or possible, a recurrence may be diagnosed by radiological imaging alone, taking the following in consideration:
o Agreement of the tumor board or a consultant neuro-radiologist that imaging changes are in keeping with recurrence.
o An interval of no less than 3 months since last (chemo)radiotherapy.
o Utilization of the RANO criteria for tumor progression.
o If needed, additional imaging sequences such as PET and perfusion MRI.
• Unifocal glioma (i.e. lesions clustering around residual surgical cavity)
• Prior course of treatment including radiotherapy with an EQD2 (α/β = 2) of at least 47Gy
• Age >= 18 years
• Karnofsky Performance Score 60 or above
• Ability of subject to understand character and individual consequences of the clinical trial (arm1)
• Patients who received re-irradiation for the recurrence of a primary brain tumor with a treatment schedule of 10x3.5Gy (arm 2).

Exclusion criteria

• Previous re-irradiation or prior radiosurgery or prior treatment with interstitial radioactive seeds.
• CE-T1 tumor diameter greater than 6cm (~reflecting a spherical tumor of 125cc).
• Time interval of less than 6 months after prior radiotherapy.
• Time interval of less than 3 weeks after last re-resection (1 week for biopsy).
• Known carcinoma < 3 years ago (excluding Carcinoma in situ of the cervix, basal cell carcinoma, squamous cell carcinoma of the skin) requiring immediate treatment interfering with study therapy.
• Women with childbearing potential without adequate contraception.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-10-2020
Enrollment:	65
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	07-04-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	23-04-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	24-05-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-12-2022

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-06-2024
Application type:	Amendment
Review commission:	METC NedMec

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	NL72766.041.20