Glioblastoma, Optimizing Logistics and Dose (GOLD).

Published: 19-05-2020
Last updated: 08-04-2024

To test whether extremely hypofractionated radiotherapy (6 x 6 Gy) is non-inferior to standard radiotherapy (30 x 2 Gy) in terms of overall survival in patients with newly diagnosed GBM. Secondary objectives are to establish and compare health...

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

Summary

ID

NL-OMON52680

Source
ToetsingOnline

Brief title
GOLD study

Condition

- Nervous system neoplasms malignant and unspecified NEC
- Nervous system neoplasms malignant and unspecified NEC

Synonym
brain tumor, glioblastoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Glioblastoma, Hypofractionated radiotherapy, Quality of Life, &bullet

Outcome measures

Primary outcome

The primary outcome measure is overall survival.

Secondary outcome

Key secondary endpoints are HRQoL (through questionnaires), cost-effectiveness,

progression-free survival, both clinical and radiological toxicity and edema

treatment

Study description

Background summary

Standard radiotherapy (RT) treatment for patients with a glioblastoma multiforme (GBM) is 30 times a 2 Gy fraction. This results in 30 visits to the hospital in an overall treatment duration of six weeks. A significant reduction of the number of fractions, i.e. extreme hypofractionation, has been proposed and was successfully tested. However, due to the important EORTC trial in 2005, where oral temozolomide chemotherapy was added to the standard of 30-fraction radiotherapy, this regimen remained the standard of care for GBM patients. The hypothesis of the GOLD study is that 6 fractions of high-precision, hypofractionated radiotherapy delivered with a higher dose per fraction is non-inferior to the standard fractionation schema and is associated with better quality of life, and lowers the costs compared to standard treatment of GBM patients.

Study objective

To test whether extremely hypofractionated radiotherapy (6 x 6 Gy) is non-inferior to standard radiotherapy (30 x 2 Gy) in terms of overall survival in patients with newly diagnosed GBM. Secondary objectives are to establish and compare health related quality of life (HRQoL), cost-effectiveness, toxicity and progression-free survival in both treatment arms.

Study design

A phase III, open-label randomized controlled non-inferiority trial with 474 patients in two arms among all participating centers, which will be added in amendments. The UMC Utrecht will expectedly include approximately 80 patients.

Intervention

The investigational arm will be treated with hypofractionated radiotherapy 6 Gy, in 6 fractions per week, combined with daily temozolomide, followed by adjuvant temozolomide. The control arm receives routine chemoradiotherapy with fractionated radiotherapy in 30 sessions of 2 Gy (standard of care) combined with daily temozolomide, followed by adjuvant temozolomide.

Study burden and risks

Participants will have to regularly visit the hospital to receive outpatient treatment, with the number of visits dependent on allocation in the investigational or control arm. After treatment, clinical follow-up will be performed by their treating physicians, among which a radiation oncologist, neuro-oncologist and internal oncologist. Additional follow-up will be performed by self-administered questionnaires. Participants will be asked to complete the HRQoL questionnaires EQ-5D-5L, EORTC QLQ-C30 and QLQ-BN20 at baseline, 1 month after start of radiotherapy and every 3 months after start of radiotherapy, and cost-utility questionnaires iMCQ and iPCQ at baseline and every 3 months after start of radiotherapy. Furthermore, they will receive a phone call every 3 months to be asked about adverse events and anti-edema-treatment, as well as to be reminded to complete the questionnaires. Finally, technical data, including MRI, CT and radiation treatment plans, acquired in standard care will be utilized.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Histological diagnosis of GBM with any MGMT-promotor methylation status and IDH1 mutation
status by multidisciplinary neuro-oncology tumor board.
• Age >= 18 years.
• KPS >=70.
• Surgical biopsy or resection performed.
• Decision of chemoradiation following the Stupp-protocol by multidisciplinary neuro-oncology
tumour board.

Exclusion criteria

• Participation in a competing trial.
• Prior overlapping intracranial radiotherapy.
• 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 and with worse prognosis than glioblastoma.
• Maximum diameter > 6cm (~ reflecting a spherical tumor volume of 125 cc).
• Unwilling or unable to undergo MRI scans.
• Contra-indication for gadolinium contrast.
• Women with childbearing potential without adequate contraception.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-11-2020
Enrollment:	474
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	19-05-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	23-04-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-03-2022
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	15-12-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-12-2023
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	NL72953.041.20