

Carbon ion radiotherapy versus fractionated stereotactic radiotherapy in patients with recurrent or progressive gliomas: the CINDERELLA trial

Submission date 10/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/02/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/02/2011	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2009-017352-26

Protocol serial number
EudraCT No.: 2009-017352-26

Study information

Scientific Title

Randomised phase I/II study to evaluate carbon ion radiotherapy versus fractionated stereotactic radiotherapy in patients with recurrent or progressive gliomas

Acronym

CINDERELLA

Study objectives

Phase I:

Phase I part of this study is conducted to choose the recommended dose (RD) of carbon ion radiotherapy for the phase II part between seven dose levels based on the dose escalation scheme.

Phase II:

The phase II part of this study is designed to demonstrate superiority in survival of carbon ion radiotherapy (experimental) to fractionated stereotactic radiotherapy (FSRT - standard) in patients with recurrent or progressive gliomas. The primary endpoints variable is overall survival time after at least 12 months of follow-up defined as time to death for any reason during the follow-up period of at least 12 months starting from date of randomisation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local medical ethics committee (Ethikkommission der Medizinischen Fakultät Heidelberg) approved on the 21st January 2010 (ref: S442-2009)

Study design

Randomised phase I/II controlled non-blinded trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Recurrent glioma

Interventions

Phase I: Dose Escalation -

Patients fulfilling the inclusion criteria will be treated with increasing total dose of carbon ion radiotherapy to evaluate the optimal carbon ion dose with respect to toxicity. The aim of this part is to determine the recommended dose (RD) of carbon ion radiotherapy for re-irradiation of recurrent gliomas.

Patients will be treated within seven increasing dose regimens starting at 10 x 3 GyE up to 16 x 3 GyE.

Phase II: Randomised Part -

Patients fulfilling the inclusion criteria will be randomised into two arms:

Arm A (Experimental Arm): Carbon Ion Radiation Therapy - total dose applied will be the RD determined in the Phase I part of the study protocol

Arm B (Standard Arm): Fractionated Stereotactic Radiotherapy with Photons - total Dose 36 Gy, 18 fractions, 2 Gy single dose

Duration of the treatment:

Control arm: 18 treatment days (standard photon precision radiotherapy 36 Gy, 2 Gy single dose)

Experimental Arm: 10 to 16 treatment days, depending on MTD determined within the phase I part of the study

Follow-up: 12 months after study treatment

Intervention Type

Other

Phase

Phase I/II

Primary outcome(s)

1. Phase I: Any Grade IV toxicity related to the study treatment according to Common Toxicity Criteria for Adverse Events (CTCAE) Grade IV
2. Phase II: Survival after re-irradiation at 12 months

Key secondary outcome(s)

1. Phase I: Survival after re-irradiation
2. Phase II:
 - 2.1. Progression-free survival at 12 months
 - 2.2. Toxicity
 - 2.3. Safety

Completion date

31/08/2014

Eligibility

Key inclusion criteria

1. Unifocal, supratentorial recurrent glioma
2. Contrast enhancement on T1-weighted magnetic resonance imaging (MRI) and/or amino acid positron emission tomography (PET)-positive high-grade tumour areas
3. Indication re-irradiation
4. Aged greater than or equal to 18 years of age, either sex
5. Karnofsky Performance Score greater than or equal to 60
6. For women with childbearing potential, (and men) adequate contraception
7. Ability of subject to understand character and individual consequences of the clinical trial
8. Written informed consent (must be available before enrolment in the trial)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Multifocal glioma or gliomatosis cerebri
2. Refusal of the patients to take part in the study
3. Previous re-irradiation or prior radiosurgery or prior treatment with interstitial radioactive seeds
4. Time interval of less than 6 months after primary radiotherapy
5. Patients who have not yet recovered from acute toxicities of prior therapies
6. Known carcinoma less than 5 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
7. Pregnant or lactating women
8. Participation in another clinical study or observation period of competing trials, respectively

Date of first enrolment

01/09/2010

Date of final enrolment

31/08/2014

Locations**Countries of recruitment**

Germany

Study participating centre

University Hospital of Heidelberg

Heidelberg

Germany

69120

Sponsor information**Organisation**

University Hospital of Heidelberg (Germany)

ROR

<https://ror.org/013czdx64>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital of Heidelberg (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes