ISRCTN01460925 https://doi.org/10.1186/ISRCTN01460925

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	[_] Prospectively registered [_] Protocol
Registration date 07/02/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/02/2011	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Jürgen Debus

Contact details
University Hospital of Heidelberg
Department of Radiation Oncology
Im Neuenheimer Feld 400
Heidelberg
Germany
69120
+49 (0)6221 56 8201
juergen.debus@med.uni-heidelberg.de

Additional identifiers

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

Protocol serial number
EudraCT No.:

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