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Carbon ion boost versus proton boost after radiochemotherapy with temozolomide in patients with primary glioblastoma

Submission date 19/07/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 08/07/2010	**Overall study status** Completed	
Last Edited 14/11/2022	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2009-014668-21

IRAS number

ClinicalTrials.gov number
NCT01165671

Secondary identifying numbers

CLEOPATRA

Study information

Scientific Title
Randomised phase II study evaluating a carbon ion boost applied after combined radiochemotherapy with temozolomide versus a proton boost after radiochemotherapy with temozolomide in patients with primary glioblastoma

Acronym
CLEOPATRA

Study objectives
The purpose of the trial is to compare a carbon ion boost to a proton boost delivered to the macroscopic tumour after combined radiochemotherapy (RT) with temozolomide (TMZ) in patients with primary glioblastoma multiforme (GBM). The aim of the study is to compare overall survival as a primary endpoint, and progression free survival, toxicity and safety as secondary endpoints.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Faculty of Heidelberg (Ethikkommission der Medizinischen Fakultät Heidelberg) approved on the 2nd of November 2009

Study design
Randomised controlled phase II study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Primary glioblastoma

Interventions

Arm A Experimental Arm
Carbon Ion Radiation Therapy as a Boost to the macroscopic tumour
Total Dose 18 Gy E, 6 fractions, 3 Gy E single dose

Arm B Standard Arm
Proton Radiation Therapy as a Boost to the macroscopic tumour
Total Dose 10 Gy E, 5 fractions, 2 Gy E single dose

In both treatment arms, the minimum follow-up will be 12 months after study treatment (for the last patient included). All other patients will be followed until 12 months after the last patient was included or until death.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Temozolomide

Primary outcome measure
Overall survival during the follow-up phase of at least 12 months (starting with initial diagnosis)

Secondary outcome measures
1. Progression-free survival
2. Safety
3. Toxicity

Overall study start date
01/11/2009

Completion date
31/10/2013

Eligibility

Key inclusion criteria
1. Histologically confirmed unifocal, supratentorial primary glioblastoma
2. Macroscopic tumour after biopsy or subtotal resection
3. Indication for combined radiochemotherapy with temozolomide
4. Prior photon irradiation of 50 Gy to the T2-hyperintense area, resection cavity, areas of contrast enhancement adding 2 - 3 cm safety margin
5. Registration prior to photon RT or within photon RT allowing the beginning of C12 greater than or equal to 4 days after completion of photon irradiation
6. Beginning of study treatment (proton or carbon ion RT) no later than 10 weeks after primary diagnosis
7. Aged greater than or equal to 18 years, either sex
8. Karnofsky Performance Score less than or equal to 60
9. Life expectancy greater than 12 weeks

10. For women with childbearing potential, (and men) adequate contraception
11. Ability of subject to understand character and individual consequences of the clinical trial
12. Written informed consent (must be available before enrolment in the trial)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Refusal of the patients to take part in the study
2. Previous radiotherapy of the brain or chemotherapy with dacarbazine (DTIC) or TMZ
3. More than 50.4 Gy applied via photon-RT prior to carbon ion RT
4. Time interval of greater than 10 weeks after primary diagnosis and beginning of study treatment (proton or carbon ion RT)
5. Patients who have not yet recovered from acute toxicities of prior therapies
6. Clinically active kidney-liver or cardiac disease
7. 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
8. Human immunodeficiency virus (HIV)
9. Pregnant or lactating women
10. Participation in another clinical study or observation period of competing trials, respectively

Date of first enrolment
01/11/2009

Date of final enrolment
31/10/2013

Locations

Countries of recruitment
Germany

Study participating centre

Department of Radiation Oncology
Heidelberg
Germany
69120

Sponsor information

Organisation
University Hospital of Heidelberg (Germany)

Sponsor details
c/o Prof. Dr. Jürgen Debus
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Sponsor type
University/education

Website
http://www.uni-heidelberg.de/university/welcome/medics-hd.html

ROR
https://ror.org/013czdx64

Funder(s)

Funder type
Research council

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) - Klinische Forschergruppe Schwerionentherapie (ref: KFO 214)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	results	06/09/2010		Yes	No