

Treatment of patients with atypical meningiomas Simpson Grade 4 and 5 with a carbon ion boost in combination with post-operative photon radiotherapy: MARCIE 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 15/04/2019	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Meningiomas are tumours of the membranes that cover the brain. Meningiomas are described as atypical when the tumor cells do not appear typical or normal. The standard treatment for patients with atypical meningioma is surgery to remove the tumour. Radiotherapy to kill any tumour cells left behind after surgery (post-operative radiotherapy) can increase the patient survival rate. The aim of this study is to find out whether a form of radiotherapy called carbon ion boost in combination with post-operative photon radiotherapy can improve the patient survival rate after 3 years.

Who can participate?

Patients aged 18 or over with atypical meningioma

What does the study involve?

All participants are treated with carbon ion boost in combination with post-operative photon radiotherapy. Survival rate, safety and toxicity are assessed.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

University Hospital of Heidelberg (Germany)

When is the study starting and how long is it expected to run for?

September 2010 to August 2016

Who is funding the study?

University Hospital of Heidelberg (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01166321

Clinical Trials Information System (CTIS)
2009-016683-36

Protocol serial number
EudraCT No.:

Study information

Scientific Title
A phase II single-arm trial of the treatment of patients with atypical meningiomas Simpson Grade 4 and 5 with a carbon ion boost in combination with post-operative photon radiotherapy

Acronym
MARClE

Study objectives
The study is designed to demonstrate that carbon ion boost in combination with post-operative photon radiotherapy can improve the progression-free survival rate after 3 years by 20%. The benchmark for largest PFS-3yR which, if true, implies that the efficacy of study treatment is too low is assumed to be 50% according to literature data with a comparable patient population (patients with atypical meningiomas Simpson grade 4 and 5 and without previous radiotherapy).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local medical ethics committee (Ethikkommission der Medizinischen Fakultät Heidelberg), 21/01/2010, ref: S444-2009

Primary study design

Interventional

Study design

Single-arm phase II trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Atypical meningioma

Interventions

No drugs are applied, only radiation therapy. There is only one treatment arm, consisting of photon radiotherapy up to 50 Gy, carbon ion boost to the macroscopic tumour up to a total dose of 18 Gy E in single doses of 3 Gy E.

Intervention Type

Other

Phase

Phase II

Primary outcome(s)

Progression-free survival rate after 3 years of follow-up

Key secondary outcome(s)

1. Overall survival at 3 years
2. Toxicity, according to EORTC criteria
3. Safety

Completion date

31/08/2016

Eligibility**Key inclusion criteria**

1. Histologically confirmed atypical meningioma
2. Macroscopic tumour after biopsy or subtotal resection
3. Simpson Grade 4 or 5
4. Prior photon radiotherapy to the clinical target volume (CTV) of 48 - 52 Gy
5. Beginning of study treatment no later than 12 weeks after surgery
6. Aged greater than or equal to 18 years of age

7. Karnofsky Performance Score greater than or equal to 60
8. For women with childbearing potential, adequate contraception
9. Ability of subject to understand character and individual consequences of the clinical trial
10. 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. Refusal of the patients to take part in the study
2. Previous radiotherapy of the brain
3. Optic nerve sheath meningioma (ONSM)
4. Time interval of greater than 12 weeks after primary diagnosis (neurosurgical intervention) and beginning of study treatment
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

31/08/2016

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?
Protocol article	protocol	09/11/2010		Yes	No