

# 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

<b>Submission date</b> 10/07/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/02/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/04/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?  
Prof. Juergen Debus  
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## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**  
2009-016683-36

**IRAS number**

**ClinicalTrials.gov number**  
NCT01166321

**Secondary identifying numbers**  
EudraCT No.:2009-016683-36

## 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**  
MARCIE

**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

**Study design**

Single-arm phase II trial

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**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**

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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

01/09/2010

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

40

**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)

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.uni-heidelberg.de>

**ROR**

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

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

University Hospital of Heidelberg (Germany)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## 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?
<a href="#">Protocol article</a>	protocol	09/11/2010		Yes	No