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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 [X] 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?
Prof. Juergen Debus
juergen.debus@med.uni-heidelberg.de

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

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
c/o Irmtraud Gürkan
Im Neuenheimer Feld 672
Heidelberg
Germany
69120
+49 (0)6221 56 7002
irmtraud.guerkan@med.uni-heidelberg.de

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?
Protocol article	protocol	09/11/2010		Yes	No