

Comparison of the functional outcome of radiosurgery and microsurgery for the treatment of cerebral metastases

Submission date 19/07/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/07/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/11/2020	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Cerebral metastases (cancer cells that have spread to the brain from tumours from other organs in the body) are an upcoming challenge for the oncological (cancer) community as the life expectancy of brain cancer patients improves and, as a consequence, the possibility of cerebral metastasis increases. Moreover, neurological integrity and functional status is becoming an important outcome parameter, as brain cancer develops into a more chronic disease. The main brain metastases treatment are microsurgical resection (a treatment technique that removes the cancer cells using specialised instruments that work on a tiny area) or different radiotherapy modalities (a type of therapy that uses high energy rays like x-rays to destroy cancer cells). Each type of treatment has different advantages as both try to keep the area as intact as possible and keep the function of the brain and protect the region of the brain that is not affected by cancer cells. However, there have been no comparisons of the two methods so far. The aim of this study is to compare the functional outcome after stereotactic radiotherapy and microsurgery of cerebral metastasis.

Who can participate?

Participants aged 18 to 80 who had their cerebral metastasis treated with one of the two types of treatment in January 2008 to September 2009.

What does the study involve?

This is a retrospective chart study that reviewed the surgical outcomes of patients who had either a stereotactic radiotherapy or microsurgery because of a cerebral metastasis located in the motor cortex. Data about their age, tumours, muscle strength, medication and complications are collected.

Outcomes from each type of treatment are compared.

What are the possible benefits and risks of participating?

There are no direct benefits or risks of participating.

Where is the study run from?

1. Department of Neurosurgery, University Clinics Bonn (Germany)
2. Department of Radiotherapy MediClin Robert Janker Clinic Bonn (Germany)

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

May 2014 to February 2016

Who is funding the study?

University Hospital Bonn (Universitätskliniken Bonn) (Germany)

Who is the main contact?

Dr Bogdan Pintea

Contact information

Type(s)

Public

Contact name

Dr Bogdan Pintea

Contact details

University Hospital Bonn (Universitätskliniken Bonn)

The Clinic and Polyclinic for Neurosurgery (Klinik und Poliklinik für Neurochirurgie)

Sigmund Freud Str. 25

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

No registration

Study information

Scientific Title

Early motor function after local treatment of brain metastases in the motor cortex region with stereotactic radiotherapy/radiosurgery or microsurgical resection: a retrospective study of two consecutive cohorts

Study objectives

The aim of this study is to compare the functional outcome after stereotactic radiotherapy and microsurgery of cerebral metastasis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

This is a retrospective study of two standard therapies, no personalized data were collected. No consulting is need for retrospective epidemiological studies.

Study design

Retrospective observational longitudinal study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Cerebral metastasis

Interventions

This is a retrospective chart review study that looks at the functional outcome of patients either with stereotactic radiotherapy or microsurgery because of a cerebral metastasis located in the motor cortex

The data that is collected from the charts include age, Karnofski performance index (KPI index), recursive partitioning analysis, tumour volume, occurrence of hemipareses before and two to three weeks after treatment (surgery or radiosurgery), muscle strength (conforming to the British Medical Research Council (BMRC) in arm and leg before and two to three weeks after the treatment they received, histology, Dexamethasone daily doses two to three weeks after treatment, local complications (intracranial bleeding, intracranial abscess, etc.) and systemic complication (pneumonia, sepsis, lung embolism, etc.).

Intervention Type

Procedure/Surgery

Primary outcome measure

Motoric function/hemiparesis is assessed by reviewing the patients notes and reports bevor treatment and three to four weeks after treatment

Secondary outcome measures

1. Need of dexamethasone/antioedema therapy are assessed by reviewing the patients notes and reports three to four weeks after treatment
2. Systemic and local complications were assessed by reviewing the patients notes and reports three to four weeks after treatment

Overall study start date

14/05/2014

Completion date

28/02/2016

Eligibility

Key inclusion criteria

1. Patients with cerebral metastasis treated either with stereotactic radiotherapy or microsurgery during the period 01/2008 to 09/2012
2. Aged 18 to 80 years old

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Retrospective cohort study with no target recruitment number. 68 patients were identified during the target period.

Total final enrolment

68

Key exclusion criteria

Missing clinical data (motor function status, histology, report)

Date of first enrolment

01/06/2014

Date of final enrolment

24/01/2016

Locations

Countries of recruitment

Germany

Study participating centre

Department of Neurosurgery, University Clinics Bonn

Sigmund Freud Str 25

Bonn

Germany

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Study participating centre

Department of Radiotherapy MediClin Robert Janker Clinic Bonn

Villenstr. 8

Bonn

Germany

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Sponsor information

Organisation

University Hospital Bonn (Universitätskliniken Bonn)

Sponsor details

The Clinic and Polyclinic for Neurosurgery (Klinik und Poliklinik für Neurochirurgie)

Sigmund Freud Str. 25

Bonn

Germany

53125

Sponsor type

University/education

Website

www.neurochirurgie-Bonn.de

ROR

<https://ror.org/01xwq93>

Funder(s)

Funder type

University/education

Funder Name

University Hospital Bonn (Universitätskliniken Bonn)

Results and Publications

Publication and dissemination plan

The manuscript has been already submitted to the Journal of Radiation Oncology.

Intention to publish date

30/09/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to legal concerns. The data was assessed and is held at the two clinical sites. However, if there is a defined request the local ethics committee can be asked for dataset release.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	13/11/2017	26/11/2020	Yes	No