ISRCTN81776764 https://doi.org/10.1186/ISRCTN81776764

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

Registration date
28/07/2017

Overall study status
Completed

Last Edited
26/11/2020

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Bonn
Germany
53127

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
53127

Study participating centre
Department of Radiotherapy MediClin Robert Janker Clinic Bonn
Villenstr. 8
Bonn
Germany
53129

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/01xnwqx93

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