

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Stereotactic biopsy vs. surgical resection in patient with diffuse low grade gliomas. Influence of initial management strategies on survival. A retrospective study.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Low grade glioma is a subgroup of brain tumors and are characterized by diffuse infiltration of brain tissue, initial slow growth but transition to malign brain tumors.

Histologic diagnosis may be obtained by either open surgical resection or stereotactic biopsy. The optimal treatment of patients with low grade glioma is still to be evaluated. There is no randomized trial which compares resection and biopsy. New evidence suggests a benefit in survival for patients who have received early surgical resection. The fact that until 2012 patients at the University Medical Center were treated by two independent departments leads to a near-randomization. This could give more evidence to one of the two treatment options.

Brief Summary in Scientific Language

Diffuse supratentorial low grade glioma in adults (DLGG) is a heterogenous neuroectodermal tumor entity accounting for about 15% of all glial brain neoplasms. It is a chronic progressive disease of the central nervous system that, by infiltrative growth and malignant transformation, leads to neurological deficits and death. Since class I evidence proving the benefit of any medical treatment does not exist, optimal management of DLGG is still controversial. An increasing body of evidence suggests, however, that an early surgical intervention is superior compared to a "watch and wait" strategy.

To date, no randomized controlled trial comparing surgical resection with biopsy has been conducted in patients with DLGG. Given the growing evidence of the benefits of an early surgical intervention, it is unlikely that such a trial will ever be performed. The closest approach to a patient randomization between biopsy and surgery originates from a retrospective population-based study comparing two Norwegian hospitals with different management strategies. Herein, a significant survival benefit (74% vs. 60% 5-year OS, 68% vs. 44% 7-year OS) was found if the principal initial management strategy of patients with DLGG was surgery. Consequently and in line with present international guidelines, surgical resection to the maximum safe extent is the suggested first-line therapy for DLGG.



A starting position comparable to that described by Jakola et al. existed at the University Medical Center Freiburg due to historical reasons. Until 2012, patients with a first diagnosis of DLGG were treated and followed either by the department of Stereotactic and Functional Neurosurgery (STX) or the Department of Neurosurgery (NS) - both operating independently - at our university medical center. This situation led to a near-randomized distribution of patients with DLGG to management either by biopsy or open resection. In the present study, the results of an early surgical intervention are compared to a management by biopsy with special emphasis on the extent of resection (EOR) and surgical morbidity.

Organizational Data

- DRKS-ID: **DRKS00009264**
- Date of Registration in DRKS: **2015/09/01**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **558/14** , **Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **D33 - Benign neoplasm of brain and other parts of central nervous system**
- ICD10: **C71 - Malignant neoplasm of brain**

Interventions/Observational Groups

- Arm 1: **Assessment of Overall Survival (OS) of all adult patients with a first histological diagnosis of diffuse low grade gliomas (DLGG) who were treated by either stereotactic biopsy or resection at the University Medical Center Freiburg between 2004 and 2012.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]*



Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Single arm study**

Blinding: [---]*

- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Overall survival (OS) from the date of the first histological diagnosis until death or November 30, 2014 or lost to follow-up, whatever is earlier.

Secondary Outcome

Operative morbidity and mortality

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Abteilung Stereotaktische und Funktionelle Neurochirurgie, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/02/01**
- Target Sample Size: **141**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

All patients 18 years or older with a first histological diagnosis of a supratentorial DLGG (WHO°II) from either a stereotactic biopsy or a neurosurgical resection between 2004 and 2012 in the Department of Neurosurgery or the Department of Stereotactic and Functional Neurosurgery of the University Medical Center Freiburg.

Exclusion criteria

Patients with evidence for a gemistocytic histology.

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/03/31**

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.