Trial Description

Title

PriCoTTF Trial: A phase I/II trial of TTFields prior and concomitant to radiotherapy in newly diagnosed glioblastoma

Trial Acronym

PriCoTTF

URL of the trial

[---]*

Brief Summary in Lay Language

This clinical study is to demonstrate if therapy with Optune® before and during standardised postoperative therapy (radiotherapy and eventually chemotherapy) in patients with newly diagnosed glioblastoma or gliosarcoma is feasible and safe. Moreover, first data on the efficacy of this combination of therapies are collected.

Brief Summary in Scientific Language

On the basis of predefined therapy-limiting toxicities, this clinical study is to demonstrate if therapy with TTFields (Optune®) before and during standardised postoperative therapy (radiotherapy and eventually chemotherapy) in patients with newly diagnosed glioblastoma or gliosarcoma is feasible and safe. Moreover, first efficacy data will be obtained.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00016667**
- Date of Registration in DRKS: **2019/02/26**
- 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.: **18-8316-MF , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

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Secondary IDs

- EUDAMED-No.
  (for studies acc. to Medical Devices act): **CIV-18-08-025247**

Health condition or Problem studied

- ICD10: **C71 - Malignant neoplasm of brain**

Interventions/Observational Groups

- Arm 1: **Patients ≤70 years old, Karnfosky Performance Status ≥60% with newly diagnosed glioblastoma or gliosarcoma are additionally treated with Optune® before and during the standard therapy (radiotherapy, possibly with chemotherapy) following the surgery**
- Arm 2: **Patients> 70 years old, Karnofsky Performance Status ≥50% with newly diagnosed glioblastoma or gliosarcoma are additionally treated with Optune® before and during the standard therapy (radiotherapy, possibly with chemotherapy) following the surgery**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **I-II**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Other**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Other**

Purpose: **Treatment**

Assignment: **Parallel**

Phase: **I-II**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **Yes**

Primary Outcome

The primary end-point is safety and tolerance and will be based on the frequency of a set of predefined Theraoy Limiting Toxicities (TLT) assessed weekly during treat-ment and up to 4 weeks after the end of radiotherapy.

Secondary Outcome

•TLT 4 weeks after radiotherapy completion until the end of treatment or tumor recurrence, whichever occurs first (overall and considering concomitant chemotherapy)
•TLT during treatment and up to 4 weeks after end of radiotherapy con-sidering concomitant chemotherapy
•Progesssion free survival (PFS)
•Overall survival (OS)
•Radiological response (RANO criteria)
•Adverse events as measured by CTCAE
•Quality of life (at end of RT, 4 weeks after the end of RT, after 3, 5 and 7 months of TTFields treatment)including subscores
•Estimation number of fully compliant patients
•Estimation of the delivered cumulative dose distribution over the treatment series for each patient from the KV-image guidance data and comparison with the planned dose distribution. Dose deviations by more than 3.5% in more than 1 cm3 within the PTV or if more than 5% in less than 1 cm3 will be considered as relevant.
•Number of patients with ≥ grade 3 skin toxicity (CTCAE) separately in-to patients with high 1 and low radiation risk.
1: high risk group: patients who received a surface dose >70% of the prescribed dose within or up to 6 mm below the skin on a scalp area are of >50 cm2

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinikum Essen, Essen**
- University Medical Center **Klinik für Strahlenheilkunde, Freiburg im Breisgau**
- University Medical Center **Klinik und Poliklinik für Neurologie, Regensburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/06/25**
- Target Sample Size: **33**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

•Pathological evidence of glioblastoma or gliosarcoma using latest WHO classification criteria
•Negative IDH status on immunohistochemistry or sequencing
•Patient received brain tumor resection or biopsy and further treatment regime foresees radiotherapy with or without concomitant chemotherapy
•General indication for whole treatment regimen was a common deci-sion of a multidisciplinary team within brain tumor board and in accordance with the national and/or international guidelines for the treatment of glioblastoma patients
•KPS ≥ 60% (Study arm A), KPS ≥ 50% (Study arm B)
•Life expectancy at least 3 months
•Participants of child-bearing age must use effective contraception
•Treatment with TTFields may start 2-4 weeks post resection and 1-2 weeks prior to radiotherapy
•Subjects with the ability to follow study instructions and likely to attend and complete all required visits
•Written informed consent of the subject

Exclusion criteria

General Exclusion Criteria:

•Subjects not able to give consent
•Subject without legal capacity who is unable to understand the nature, scope, significance, and consequences of this clinical trial
•Simultaneously participation in another clinical trial or participation in any

clinical trial involving administration of an investigational medicinal product within 30 days prior to clinical trial beginning
•Subjects with a physical or psychiatric condition which at the investigator's discretion may put the subject at risk may confound the trial results or may interfere with the subject's participation in this clinical trial
•Known or persistent abuse of medication, drugs or alcohol
Exclusion criteria regarding special restrictions for females:
•Current or planned pregnancy or nursing women
•Females of child-bearing potential, who are not using and not willing to use medically reliable methods of contraception for the entire study duration (such as oral, injectable, or implantable contraceptives, or intrauterine contraceptive devices) unless they are surgically sterilized / hysterectomized or there are any other criteria considered sufficiently reliable by the investigator in individual cases

Indication-specific exclusion criteria:

•Infra-tentorial tumor
•Significant comorbidities at baseline, which would prevent possible chemotherapy, including:
oPlatelet count < 100/nl
oAbsolute neutrophil count (ANC) < 1.5/nl
oAST or ALT > 3 times the upper limit of normal
oTotal bilirubin above the normal range
oSerum creatinine > 1.7 mg/dl
•Patients with clinically significant liver-, renal- or blood disorder
•Patients with known additional significant neurological disease (e.g. primary seizure disorder*, dementia, progressive degenerative neuro-logical disease, meningitis or encephalitis, hydrocephalus with in-creased intracranial pressure)
***Patients with brain tumor-related epilepsy, seizure-free under antiepileptic therapy are eligible**
•Documented allergy to conductive hydrogel (e.g. ECG (electrocardio-gram) sticker or TENS (transcutaneous electrical nerve stimulation) electrodes)
•Active implanted medical device (e.g. deep brain stimulators, spinal cord stimulators, vagus nerve stimulators, pacemakers, defibrillators and programmable shunts)or documented clinically significant arrhythmias
•Skull defect (e.g. missing bone with no replacement) and bullet frag-ments in the skull
•History of hypersensitivity reaction to temozolomide or lomustine
•History of HIV infection

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 ongoing**
- Study Closing (LPLV): **[---]***

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.*