

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

Trial Description

Title

Analysis of glioblastoma-metabolism by MRI-Spectroscopy

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In a joint research project of the clinic of neurosurgery and the clinic of neuroradiology Kiel we aim to examine the metabolism of intracerebral Tumors with MR-spectroscopy. This research focused on getting further information about the so called Warburg-effect. This effect describes the suspicion that tumor cells gain energy through an oxygen-independent metabolism despite the availability of oxygen. This mechanism could enable the tumor cells to cover the demand of the high energy requirement caused by fast tumor growth.

By a special MR-examination, the MR-spectroscopy, it is possible to measure the morphological distribution of metabolites and quantify them. We are especially interested in the distribution of lactate, which is one if the produced metabolites concerning the Warburg-effect.

Brief Summary in Scientific Language

The Glioblastoma multiforme is the most common and most malign primary brain tumor. Currently there are still no curative therapy-regimes available. Responsible for this poor prognosis are b.o. the fast growth of the tumor although there are no energy substrates available and the early migration of the tumor cells. To enable this aggressive attributes the tumor cells are able to undergo molecular changes, which f.e. lead to a change of the metabolism.

Already in the 20th century a German scientist and later Nobelist Otto Warburg hypothesized that the raised lactate-levels of Tumor cells are caused by an oxygen independent glycolysis of the cells. This process, since then named Warburg effect and hallmark of severe tumorentities, seems to be an adjustment mechanism enabling the tumor cells to cover the high energy demand caused by fast tumor growth.

Meanwhile a diagnostic procedure found its way into daily work which can provide important information about the metabolism of intracranial Tumors without being invasive or using ionizing radiation. The hereby described MR-spectroscopy just takes a few minutes and is already used to further distinguish between primary brain tumors and metastasis. Lactate is one of the hereby measured metabolites. Molecular-biological examinations let us suggest that lactate is mostly exported in the hypoxic center of the Glioblastoma and gets again absorbed in the vesiculated

tumor parts for producing energy. In this field further detailed studies using MR-spectroscopy are currently not available. In this setting we plan to exploit preoperative MR-spectroscopies of brain tumors.

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00014760**
- Date of Registration in DRKS: **2019/03/05**
- 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.: **D 444/18 , Ethikkommission der Christian-Albrechts-Universität zu Kiel**

Secondary IDs

Health condition or Problem studied

- ICD10: **C71.9 - Malignant neoplasm: Brain, unspecified**

Interventions/Observational Groups

- Arm 1: **In the study, an MRI spectroscopy (a measurement lasting only a few minutes) is carried out in order to be able to detect any differences in tumor metabolism in the tumor center and peripheral area. All patients are examined who are suspected of having a brain-specific tumor and who have given their consent after detailed information. A total of at least 10 patients should be examined.**

Characteristics

- Study Type: **Non-interventional**
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Study Type Non-Interventional: **Other**

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

Primary Outcome

Minimum 10 patients should be examined with MRS (magnetic resonance spectroscopy). The results of edge and central regions of the tumor will be compared.

Secondary Outcome

The data-research is to be continued for about three years.

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- University Medical Center **Neurochirurgie / Neuroradiologie, Kiel**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/05/14**
- Target Sample Size: **20**
- 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

Intracranial tumors

Exclusion criteria

in need of protection (children)

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): **2020/04/15**

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.