

Trial Description

Title

Multicenter, randomized, controlled trial of remote ischemic preconditioning in the surgical management of gliomas

Trial Acronym

RIP_G

URL of the trial

http://-

Brief Summary in Lay Language

Regarding neurosurgical tumor resections perioperative ischemia (stroke) is a frequent phenomenon and often responsible for postoperative neurological deficits. In particular in the field of cardiac surgery, but also in other fields it has been shown that the application of ischemic stimulus, not only in the target organ, but also elsewhere in the body, can prevent ischemia in some patients. This is described as ischemic preconditioning. In Neurosurgery it has not been sufficiently evaluated. This Study evaluates the effect of ischemic preconditioning on the occurrence of preoperative ischemia in patients with gliomas (intrinsic brain tumors).

Brief Summary in Scientific Language

Regarding neurosurgical tumor resections perioperative ischemia is a frequent phenomenon and often responsible for postoperative neurological deficits. In particular in the field of cardiac surgery, but also in other fields it has been shown that the application of ischemic stimulus, not only in the target organ, but also elsewhere in the body, can prevent ischemia in some patients. This is described as ischemic preconditioning. In Neurosurgery it has not been sufficiently evaluated. This Study evaluates the effect of ischemic preconditioning on the occurrence of preoperative ischemia in patients with gliomas.

Randomization of by computer in two study arms (ratio 1:1). Induction of ischemic preconditioning: A blood pressure cuff is attached to the arm (contralateral to the brain tumor) and inflated three times for 5 minutes at 200 mmHg in the treatment group after induction of anesthesia. Between the cycles, the cuff pressure is released to allow reperfusion. In the placebo group, a blood pressure cuff is only attached to the arm. The other anesthetic procedures correspond to the standard procedures for resection of brain tumors. The postoperative MRI will be evaluated for the volume of the postoperative ischemia. Additionally postoperative neurological status between the two groups will be compared. By exosome and metabolite analysis in a subgroup of patients the effect of ischemic preconditioning will be characterized.

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



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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00011175**
- Date of Registration in DRKS: **2016/10/11**
- 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.: **339/16 S , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **C71.9 - Malignant neoplasm: Brain, unspecified**
- ICD10: **I63.9 - Cerebral infarction, unspecified**
- Free text: **Glioma, brain tumor**

Interventions/Observational Groups

- Arm 1: **A blood pressure cuff is attached to the arm (contralateral to the brain tumor) and inflated three times for 5 minutes at 200 mmHg in the treatment group after induction of anesthesia. Between the cycles, the cuff pressure is released to allow reperfusion.**
- Arm 2: **In the placebo group, a blood pressure cuff is attached to the arm, only.**

Characteristics

- Study Type: **Interventional**
-



Study Type: **Interventional**

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

- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **patient/subject, investigator/therapist, assessor, data analyst**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Volume of ischemia assessed by direct postoperative cMRI (<72h)

Secondary Outcome

neurological deficits (NIHSS one week postoperative/discharge), clinical status (KPS one week postoperative/discharge), time to tumor progression, overall survival, hemodynamic parameters during surgery

Countries of recruitment

- DE **Germany**
- AT **Austria**

Locations of Recruitment

- University Medical Center **München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/07/20**
- Target Sample Size: **440**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

Patients with suspected primary brain tumor for which surgical resection is planned;
Consent to participate in the study;
Age > 18.

Exclusion criteria

Non OP-enabled patient (from anesthesiological, medical or surgical view);
Patients who have to be operated immediately without extensive preoperative diagnosis;
Lack of surgical consent;
Lack of consent to participate in the study;
Pregnancy;
Age < 18 years;
History of peripheral arterial disease (PAD) or DM with use of oral antidiabetics.

Addresses

■ Primary Sponsor

Neurochirurgische Klinik und Poliklinik, Klinikum rechts der Isar
Mr. PD Dr Jens Gempt
Ismaninger Str. 22
81675 München
Germany

Telephone: **08941409722**

Fax: **08941404889**

E-mail: **jens.gempt at tum.de**

URL: [---]*

■ Contact for Scientific Queries

Neurochirurgische Klinik und Poliklinik, Klinikum rechts der Isar
Mr. PD Dr Jens Gempt
Ismaninger Str. 22
81675 München
Germany



Contact for Scientific Queries

Neurochirurgische Klinik und Poliklinik, Klinikum rechts der Isar

Mr. PD Dr Jens Gempt

Ismaninger Str. 22

81675 München

Germany

Telephone: **08941409722**

Fax: **08941404889**

E-mail: **jens.gempt at tum.de**

URL: [---]*

■ Contact for Public Queries

Neurochirurgische Klinik und Poliklinik, Klinikum rechts der Isar

Mr. PD Dr Jens Gempt

Ismaninger Str. 22

81675 München

Germany

Telephone: **08941409722**

Fax: **08941404889**

E-mail: **jens.gempt at tum.de**

URL: [---]*

Sources of Monetary or Material Support

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

Neurochirurgische Klinik und Poliklinik, Klinikum rechts der Isar

Mr. PD Dr Jens Gempt

Ismaninger Str. 22

81675 München

Germany

Telephone: **08941409722**

Fax: **08941404889**

E-mail: **jens.gempt at tum.de**

URL: [---]*

Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): [---]*

DRKS-ID: **DRKS00011175**

Date of Registration in DRKS: **2016/10/11**

Date of Registration in Partner Registry or other Primary Registry: [---]*

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.*