

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

Trial Description

Title

LOGGIC Core BioClinical Data Bank

Trial Acronym

LOGGIC Core

URL of the trial

[---]*

Brief Summary in Lay Language

Establishment of a molecular and clinical database for pediatric low-grade gliomas. The data will be used to improve the understanding of the tumor biology of the disease. For this purpose, state-of-the-art techniques are used to obtain a "fingerprint" of each individual tumor.

Brief Summary in Scientific Language

The overall aim of the LOGGIC Core BioClinical Data Bank (LOGGIC Core) is to set up a molecular and clinical data bank for pediatric low grade gliomas (LGG). The data will be used to enhance the understanding of tumorbiology of the disease but also to correlate molecular subgroups of LGG with clinical outcome. In addition, the registry will serve as a data bank for providing molecular data for other trials of the LOGGIC program. Tumor samples will be collected as part of the routine standard of care clinical management of LGG patients. The registry is a non-interventional collection of molecular and clinical data. State-of-the-art molecular profiling technologies will be applied to get a "fingerprint" of each individual tumour. The treating physicians will have access to the molecular information/targets of their patients and carry the full responsibility as to whether and in which way they use these data for clinical use. LOGGIC Core will collect clinical and histological baseline data and provide molecular genetic data to other trials of the LOGGIC program including the LOGGIC Europe and other clinical trials. As such, LOGGIC Core is an integral and essential part of the wider LOGGIC concept.

Any patient with newly diagnosed LGG either by histology and/or imaging will be registered into LOGGIC Core after informed consent. With registration in LOGGIC Core, formalin-fixed paraffin-embedded (FFPE) and fresh-frozen tissue and blood need to be submitted for molecular diagnostics .

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00019035**
- Date of Registration in DRKS: **2019/11/29**
- 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.: **S-064/2019 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- Free text: **Low Grade Glioma**
- ICD10: **D33 - Benign neoplasm of brain and other parts of central nervous system**
- ICD10: **D43 - Neoplasm of uncertain or unknown behaviour of brain and central nervous system**

Interventions/Observational Groups

- Arm 1: **From samples taken during the routine (tumor tissue and blood), a molecular fingerprint of the tumor is generated by DNA methylation profile and RNA sequencing. Using this data, it is possible for the attending physician at the participating center to select potential AMG studies for the patient as an additional option to standard of care therapy. However, LOGGIC Core does not provide therapy advice, but is a purely scientific approach.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Other**
- Blinding: [---]*
- Who is blinded: [---]*

Study Type: **Non-interventional**

Study Type Non-Interventional: **Other**

Allocation: **Other**

Blinding: [---]*

Who is blinded: [---]*

- Control: **Other**
- Purpose: **Other**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Establishment of a molecular and clinical data base for pediatric low grade glioma

Secondary Outcome

To collect molecular tumour characteristics of LGG patients for exploratory analysis of biomarker and clinical outcome.

Countries of recruitment

- **DE Germany**
- **CH Switzerland**
- **NL Netherlands**
- **AT Austria**
- **NO Norway**
- **AU Australia**
- **BE Belgium**
- **DK Denmark**
- **FI Finland**
- **GR Greece**
- **UK United Kingdom**
- **IE Ireland**
- **IT Italy**
- **SE Sweden**
- **HU Hungary**
- **ES Spain**
- **CZ Czech Republic**
- **PT Portugal**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/04/05**
- Target Sample Size: **5000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **0 Years**
- Maximum Age: **20 Years**

Additional Inclusion Criteria

- **Age < 21 years.**
- **Histologically verified LGG**
Exceptions (i.e. MRI based diagnosis) can be accepted only where a biopsy would pose an unacceptable risk to damage of eloquent brain structures.
- **Primary diagnosis or progression following initial observation.**
- **Fresh frozen and paraffin tumour material together with blood available for molecular diagnostics.**
In the case the date of diagnosis is earlier as the start of LOGGIC Core in a country, submission of fresh frozen and paraffin tumour material together with blood is mandatory with no exceptions (in other words, one can include "retrospective cases" only if material is available).
- **Before patient registration, written informed consent, including data and tumour material transfer, must be given according to ICH/GCP, and national/local regulations.**
- **No previous treatment (except surgery)**

Exclusion criteria

any previous treatment with chemo/radio therapy, excluding surgery

Addresses

■ Primary Sponsor

Hopp Kindertumorzentrum Heidelberg
Mr. Prof. Dr. Olaf Witt
Im Neuenheimer Feld 430
69120 Heidelberg
Germany

Telephone: **+49 6221-42-3570**

Fax: [---]*

E-mail: **loggic at kitz-heidelberg.de**

URL: [---]*

■ Contact for Scientific Queries

Hopp Kindertumorzentrum Heidelberg (KITZ)
Mr. Prof. Dr. Olaf Witt
Im Neuenheimer Feld 430
69120 Heidelberg
Germany

Telephone: **+49 6221 42-3570**

Fax: [---]*

E-mail: **o.witt at kitz-heidelberg.de**

URL: [---]*

■ Contact for Public Queries

Hopp Kindertumorzentrum Heidelberg
Ms. Dr. Claudia Caspar
Im Neuenheimer Feld 130.3
69120 Heidelberg
Germany

Telephone: [---]*

Fax: [---]*

E-mail: **claudia.caspar at kitz-heidelberg.de**

URL: [---]*

Sources of Monetary or Material Support

■ Private sponsorship (foundations, study societies, etc.)

The Brain Tumour CharityHartshead House

Mr. Dr. David Jenkinson

61-65 Victoria Road

GU14 7PA Hampshire

Telephone: **+44 (0) 1252 418190**

Fax: [---]*

E-mail: [---]*

URL: **thebraintumourcharity.org**

Status

■ Recruitment Status: **Recruiting ongoing**

■ Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting started": [---]*

■ Reason, if Reason for Recruiting Stop "Other": [---]*

■ Study Closing (LPLV): [---]*

■ Number of Participants in Germany after Recruiting complete: [---]*

■ Total Number of Participants (all Sites worldwide) after Recruiting complete: [---]*

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.