

Trial Description

Title

A monocenter registry study to document clinical, biological and quality of life parameters in patients with gastrointestinal tumors

Trial Acronym

GASTRY

URL of the trial

[---]*

Brief Summary in Lay Language

Documentation of patient data of patients with gastrointestinal tumors or unknown primary including measurement of life quality.

Brief Summary in Scientific Language

A monocenter registry for documenting clinical, biological and quality of life parameters in patients with gastrointestinal tumors.

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

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00018788**
- Date of Registration in DRKS: **2020/01/14**
- 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.: **F-2019-066 , Ethik-Kommission bei der Landesärztekammer Baden-Württemberg**

Secondary IDs



Health condition or Problem studied

- Free text: **Gastrointestinal tumors**
- Free text: **CUP-SYNDROM**
- ICD10: **C15-C26 - Malignant neoplasms of digestive organs**
- ICD10: **C80 - Malignant neoplasm, without specification of site**

Interventions/Observational Groups

- Arm 1: **Documentation of clinical data including molecular diagnostic results and quality of life in patients with gastrointestinal tumors or unknown primary.**

Characteristics

- 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

Comparison of Overall Survival between patients who received a molecular-stratified therapy after first tumor progression at latest and patients who did not.

Secondary Outcome

- **Comparison of PFS with molecular-stratified therapy and preceding therapy (PFS-Ratio)**
- **Evaluation of efficacy of therapies with pre-defined parameters**
- **Evaluation of Tumor board decisions**
- **Development of a molecular map based on NGS analyses, sub-typing of molecular signalling pathways**
- **Correlation between mutational status and clinical parameters resp. quality of life**

- Identification of prognostic and predictive factors

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **SLK-Kliniken Heilbronn GmbH, Heilbronn**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/01/01**
- Target Sample Size: **100**
- 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

- **Patients with advanced GI Tumor or CUP Syndrome and indication of systemic treatment**
- **Molecular examination indicated**
- **Age ≥ 18 Jahre**
- **Written informed consent**

Exclusion criteria

- **Severe neurologic or psychiatric disorders which interfere with the patient's ability to provide informed consent**

Addresses

- **Primary Sponsor**
SLK-Kliniken Heilbronn GmbH



Primary Sponsor

SLK-Kliniken Heilbronn GmbH
Am Gesundbrunnen 20-26
74078 Heilbronn
Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

■ **Contact for Scientific Queries**

SLK-Kliniken Heilbronn GmbH
Ms. Dr. rer.nat. Dilyana Vladimirova
Am Gesundbrunnen 20-26
74078 Heilbronn
Germany

Telephone: **+49-7131-49-28212**

Fax: **+49-7131-49-47-28700**

E-mail: **dilyana.vladimirova at slk-kliniken.de**

URL: **www.slk-kliniken.de**

■ **Contact for Public Queries**

SLK-Kliniken Heilbronn GmbH
Mr. Josef Huber
Am Gesundbrunnen 20-26
74078 Heilbronn
Germany

Telephone: **+49-7131-49-28700**

Fax: **+49-7131-49-47-28700**

E-mail: **josef.huber at slk-kliniken.de**

URL: **www.slk-kliniken.de**

Sources of Monetary or Material Support

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

SLK-Kliniken Heilbronn GmbH
Am Gesundbrunnen 20-26
74078 Heilbronn
Germany

Telephone: [---]*

Fax: [---]*

DRKS-ID: **DRKS00018788**

Date of Registration in DRKS: **2020/01/14**

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



Deutsches Register
Klinischer Studien

German Clinical
Trials Register

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

SLK-Kliniken Heilbronn GmbH

Am Gesundbrunnen 20-26

74078 Heilbronn

Germany

Telephone: [---]*

Fax: [---]*

E-mail: [---]*

URL: [---]*

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.