Trial Description

Title

Retro- and prospective observational study evaluating MSI and KRAS for prognosis of early colorectal cancer stage I, II and III

Trial Acronym

ColoPredict Plus 2.0 Register

URL of the trial

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Brief Summary in Lay Language

Colopredict Plus 2.0 molecular registry captures clinical data, blood and tissue of patients with colon cancer (CC) stages I, II and III retro- and prospectively over a period of 5 years after primary diagnosis. Primary objective is the evaluation of microsatellite instability (MSI) combined with KRASmutations regarding the prognosis of CC stage II without clinical risk factors. Next to an analysis of MSI and KRAS in the resected CC tissue samples, clinical and histopathological data are being captured. Primary objective is the recurrence free survival (RFS) after 5 years (combined: CC recurrence or death of any cause).

Brief Summary in Scientific Language

Identification of a marker panel for therapy in CRC

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

Yes

Description IPD sharing plan

On request our study may serve as screening platform for other Trials.

Organizational Data

- DRKS-ID: **DRKS00004305**
- Date of Registration in DRKS: **2013/01/09**
- 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.: **4449-12, 6151-17 , Ethik-Kommission der**

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Medizinischen Fakultät der Ruhr-Universität Bochum

Secondary IDs

Health condition or Problem studied

- ICD10: **C18 - Malignant neoplasm of colon**

Interventions/Observational Groups

- Arm 1: **Each Patient will be treated according to his physicians therapeutic strategy - there is no intervention and no arming.**
  Tumor tissue will be tested for MSI and RAS, and we will collect relevant histopathological and clinical data.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Epidemiological study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

5-year RFS of MSI/KRAS WT patients versus MSS/KRAS MT patients with colon cancer stage II without risk factors

Secondary Outcome

5-year RFS of MSI/KRAS WT patients versus MSS/KRAS MT patients with colon cancer stage II with risk factors
OS, DFS of patients with colon cancer stage II
RFS, DFS and OS of patients with colon cancer stage III

explorative:
Identify molecular signature for patients stage II without risk factors
To identify patients that are clinically and/or molecularly eligible for interventional trials (optional).
establish a participatory decision making strategy

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/09/01**
- Target Sample Size: **8000**
- 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

Patients, treated at participating sites are eligible for participation if they fulfill all oft he following criteria:
prospective enrollment:
• Male or female patient with CC UICC stage I, II or III
• Cooperating pathology willing to provide tissue samples for research according to study protocol
• Age ≥ 18 years and able to understand the concept of the registry and give informed consent
• signed informed consent for registry participation according to ICH-GCP guidelines

retrospective enrollment:
• primary diagnosis since 1st January 2006
• other inclusion criteria according to protocoll version 5.1.1

Exclusion criteria

patients that
• do not fulfill inclusion criteria
• withdraw consent to participate

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**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting 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.*