Trial Description

Title

5-Fluorouracil (5-FU), folinic acid and irinotecan (FOLFIRI) versus 5-FU and folinic acid as second-line chemotherapy in patients with biliary tract cancer (IRIBIL): a randomized open-label phase 2 study

Trial Acronym

AIO-YMO/HEP-0316-IRIBIL

URL of the trial

http://liegt noch nicht vor

Brief Summary in Lay Language

This study will evaluate the combination therapy of FOLFIRI in comparison to 5-FU/folinic acid monotherapy in patients with advanced cholangiocarcinoma or gallbladder cancer.

Brief Summary in Scientific Language

This randomized study will evaluate the combination therapy of FOLFIRI in comparison to 5-FU/folinic acid monotherapy. It will be evaluated if the combination therapy shows an improvement in progression-free survival. Furthermore, overall survival, the time until progression and the quality of live will be assessed.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00012595**
- Date of Registration in DRKS: **2017/06/16**
- 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.: **157/16F , Ethikkommission des Fachbereichs Humanmedizin der Johann-Wolfgang-Goethe-Universität Frankfurt am Main**

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Secondary IDs

- EudraCT-No.
  (for studies acc. to Drug Law): **2015-004028-69**

Health condition or Problem studied

- ICD10: **C22 - Malignant neoplasm of liver and intrahepatic bile ducts**
- ICD10: **C23 - Malignant neoplasm of gallbladder**

Interventions/Observational Groups

- Arm 1: **5-Fluoruracil, Folinic acid and Irinotecan (FOLFIRI), infusion, every 2 weeks**
- Arm 2: **5-Fluoruracil, Folinic acid, infusion, every 2 weeks**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

Determination of the progression free survival (PFS)
Treatment will be continued until one of the following occurs:
• progressive disease (PD),
• not tolerable toxicity
• patient's wish,
• other reasons according to which continuation of treatment is not in the patient's best interest

Secondary Outcome

Determination of
• overall survival (OS)
• time to progression (TTP) by RECIST 1.1, every 8 weeks
• overall response rate (either complete response, CR, or partial response, as measured by RECIST 1.1
• safety profile
• quality of life (EORTC QLQ-C30 questionnaire), every 2 weeks

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Medizinische Klinik 1, Frankfurt a.M.**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/08/10**
- Target Sample Size: **56**
- 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

• Written informed consent granted prior to initiation of any study specific screening procedures
• Patients with histologically confirmed CCA or GB-CA not suitable for resection or metastatic
• Progressive disease after undergoing a systemic chemotherapy with a platin-derivate (Oxaliplatin, Cisplatin or Carboplatin) and Gemcitabine or progressive disease within 3 months after cessation of chemotherapy
• Age < 18 years
• Performance status ECOG 0-2
• Normal organ and bone marrow function defined as:
o Hematopoetic: absolute neutrophil count >1,500/mm3, platelet count >75,000/mm3, hemoglobin >9 g/dL
o INR ≤ 1.5
o Hepatic: AST or ALT < 5 x ULN, bilirubin ≤ 2 mg/dl
o Renal: serum creatinine < 1.5 x ULN
• Child Pugh stage A in patients with cirrhosis (Appendix 21.2)
• Women of childbearing potential must have a negative serum pregnancy test performed within 7 days prior to the randomization
• Male or female patients of child-bearing potential must agree to use oral contraception, intrauterine device, bilateral tubal occlusion, vasectomised partner or avoidance of intercourse during the study and for 180 days after last investigational drug dose received

Exclusion criteria

• CCA or GB-CA amendable for surgical resection
• Prior radiation therapy, chemoradiation, transarterial chemoembolisation (TACE), Radiofrequency ablation (RFA) or selective intraarterial Radiotherapy (SIRT) within the last 3 months, radiation of symptomatic bone metastasis is allowed
• Concomitant photodynamic therapy or intraductal radiofrequency ablation within the last 8 weeks
• Child Pugh stage B or C (> 6 points) in patients with cirrhosis
• Massive, uncontrolled ascites
• Systemic anticancer chemotherapy other than Gemcitabin and a platin derivate (Cisplatin, Carboplatin or Oxaliplatin)
• Cardiac disease: congestive heart failure > class II NYHA
• Known uncontrolled brain metastasis
• History of bone marrow or organ allograft
• Active clinically serious infections > CTCAE grade 2 beside of chronic hepatitis C virus infection
• Major surgery within 4 weeks of first dose of study drug, port implantation is allowed
• Known or suspected allergies to 5-FU, folinic acid, irinotecan or other constituent materials or a known dihydropyrimidin-dehydrogenase deficiency
• Previous cancer that is distinct in primary site or histology from CCA or GB-CA except cervical cancer in situ, treated basal cell carcinoma, superficial bladder tumors or any cancer curatively treated 3 years prior to study entry
• Substance abuse, medical or psychological condition that may interfere with the patient´s participation in the study
• Participation in another clinical trial with any investigational study drug (whatever the use, curative, prophylactic or diagnostic intent) within 30 days prior to enrollment
• Pregnancy or breast feeding women

• Concomitant treatment with Brivudin, Sorivudin or their analogues or use of St. John's wort
• severe diarrhea
• inflammatory bowel disease and/or ileus
- • concomitant use of live attenuated vaccines during and 6 months after the end of chemotherapy
• Incapability to give valid informed consent (including patients who are dependent on the sponsor or the investigator)

Addresses

■ **Primary Sponsor**

Dekanat des Fachbereichs MedizinUniversitätsklinikum der Goethe-Universität Frankfurt
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Telephone: **[---]***
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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

  medac Gesellschaft für klinische Spezialpräparate mbH
  Theaterstraße 6
  22880 Wedel
  Germany

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- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

  Universitäres Zentrum für Tumorerkrankungen (UCT) über das Hessisches Onkologie Konzept)
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  60590 Frankfurt
  Germany

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  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.*