Adjuvant Chemotherapy With Gemcitabine and Cisplatin Compared to Observation After Curative Intent Resection of Biliary Tract Cancer (ACTICCA-1)

This study is currently recruiting participants. (see Contacts and Locations)

Verified June 2014 by Universitätsklinikum Hamburg-Eppendorf

Sponsor:
Universitätsklinikum Hamburg-Eppendorf

Collaborators:
Deutsche Krebshilfe e.V., Bonn (Germany)
medac GmbH

Information provided by (Responsible Party):
Universitätsklinikum Hamburg-Eppendorf

ClinicalTrials.gov Identifier:
NCT02170090

First received: June 18, 2014
Last updated: June 20, 2014
Last verified: June 2014
History of Changes

Purpose

This is a multicentre, prospective, randomized, controlled phase III trial designed to assess the clinical performance of gemcitabine with cisplatin and observation vs. observation alone in patients after curative intent resection of cholangiocarcinoma and muscle invasive gall bladder carcinoma.

Condition	Intervention	Phase
Cholangiocarcinoma Gall Bladder Carcinoma	Drug: Gemcitabine Drug: Cisplatin Other: Observation	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: Adjuvant Chemotherapy With Gemcitabine and Cisplatin Compared to Observation After Curative Intent Resection of Cholangiocarcinoma and Muscle Invasive Gall Bladder Carcinoma (**ACTICCA-**1 Trial)

Resource links provided by NLM:

Genetics Home Reference related topics: bladder cancer

MedlinePlus related topics: Bladder Cancer

Drug Information available for: Cisplatin Gemcitabine Gemcitabine hydrochloride

Genetic and Rare Diseases Information Center resources: Biliary Tract Cancer Gall Bladder Cancer

U.S. FDA Resources

Further study details as provided by Universitätsklinikum Hamburg-Eppendorf:

Primary Outcome Measures:

- Disease free survival (DFS) [Time Frame: Disease free survival rate at 24 months (DFSR@24)] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Disease free survival rate at 24 months (DFSR@24) [Time Frame: 24 months] [Designated as safety issue: Yes]
- overall survival [Time Frame: 84 months] [Designated as safety issue: Yes]
- Safety and tolerability (assessed by the rate of patients with adverse events according to NCI CTC AE v4.03) [Time Frame: 24 months] [Designated as safety issue: Yes]
- Quality of life [Time Frame: 48 months] [Designated as safety issue: No]
- Function of biliodigestive anastomosis (in terms of surgical revision, requirement for PTCD) [Time Frame: 48 months] [Designated as safety issue: No]
- Rate and severity of biliary tract infections [Time Frame: 48 months] [Designated as safety issue: No]
- Patterns of disease recurrence [Time Frame: 48 months] [Designated as safety issue: No]
- locoregional control (assessed by the rate of patients with hepatic or locoregional recurrence) [Time Frame: 48 months] [Designated as safety issue: No]

Estimated Enrollment:	450
Study Start Date:	April 2014
Estimated Study Completion Date:	April 2022
Estimated Primary Completion Date:	April 2019 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: gemcitabine plus cisplatin Therapy will be administered on days 1 and 8 every 3 weeks. Cisplatin (25 mg per square meter of body-surface area) will be administered over 1 hour (1 liter of 0.9% saline including cisplatin, 20 mmol of potassium chloride, and 8 mmol of magnesium sulfate followed by 500 ml of 0.9% saline over 30 minutes) followed by gemcitabine (1000 mg per square meter) as a 30-minute infusion and Observation	Drug: Gemcitabine Drug: Cisplatin Other: Observation
Observation alone Observation alone	Other: Observation

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

All enrolled patients will postoperatively be assessed for eligibility for the treatment phase. Additionally patients not previously enrolled into the trial for whatever reason (e.g. incidental finding during surgery) will be evaluated for eligibility.

- Histologically confirmed adenocarcinoma of biliary tract (intrahepatic, hilar or extrahepatic cholangicarcinoma or muscle invasive gallbladder carcinoma) after radical surgical therapy with macroscopically complete resection (mixed tumor entities (HCC/CCA) are excluded)
- Macroscopically complete resection (R0/1) within 6 (-16) weeks before scheduled start of chemotherapy
- ECOG 0-1
- Age >18 years
- Adequate hematologic function
- Adequate liver function
- Adequate renal function
- No active uncontrolled infection, except chronic viral hepatitis under antiviral therapy
- No concurrent treatment with other experimental drugs or other anti-cancer therapy, treatment in a clinical trial within 30 days prior to randomization
- Negative serum pregnancy test within 7 days of starting study treatment in pre-menopausal women and women <1 year after the onset of menopause (Note: a negative test has to be reconfirmed by a urine test, should the 7-day window be exceeded)

Criteria for initial study enrolment

- Written informed consent
- No prior chemotherapy for cholangiocarcinoma
- No previous malignancy within 3 years or concomitant malignancy, except: non-melanomatous skin cancer or adequately treated in situ cervical cancer
- No severe or uncontrolled cardiovascular disease (congestive heart failure NYHA III or IV, unstable angina pectoris, history of myocardial infarction in the last 3 months, significant arrhythmia)
- Absence of psychiatric disorder precluding understanding of information of trial related topics and giving informed consent
- No serious underlying medical conditions (judged by the investigator), that could impair the ability of the patient to participate in the trial
- Fertile women (< 1 year after last menstruation) and procreative men willing and able to use effective means of contraception (oral contraceptives, intrauterine contraceptive device, barrier method of contraception in conjunction with spermicidal jelly or surgically sterile)
- No pregnancy or lactation

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02170090

Locations

Germany

University Medical Center Aachen — **Not yet recruiting**
Aachen, Germany
Contact: Tom Luedde, MD 0241 8035609 tluedde@ukaachen.de

Charite Berlin — **Recruiting**
Berlin, Germany
Contact: Marianne Sinn, MD 030 450 55 3222 marianne.sinn@charite.de

University Medical Center Bonn — **Not yet recruiting**
Bonn, Germany
Contact: Kalff, Prof 0049 228 287 15327 kalff@uni-bonn.de

University Medical Center Carl Gustav Carus — **Not yet recruiting**
Dresden, Germany
Contact: Gunnar Folprecht, MD 0351 458 4794 gunnar.folprecht@uniklinikum-dresden.de

University Medical Center Duesseldorf — **Not yet recruiting**
Duesseldorf, Germany
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University Medical Center Essen — **Not yet recruiting**
Essen, Germany
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University of Frankfurt — **Not yet recruiting**
Frankfurt, Germany
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University Medical Center Freiburg — **Recruiting**
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University Medical Center Hamburg-Eppendorf — **Recruiting**
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University of Hannover — **Not yet recruiting**
Hannover, Germany
Contact: Arndt Vogel, Prof vogel.arndt@mh-hannover.de

University of Heidelberg — **Not yet recruiting**
Heidelberg, Germany
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University of Saarland — **Not yet recruiting**
Homburg, Germany
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University Medical Center Jena — **Recruiting**
Jena, Germany
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University of Leipzig — **Not yet recruiting**
Leipzig, Germany
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University of Magdeburg — **Not yet recruiting**
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Johannes Gutenberg University of Mainz — **Not yet recruiting**
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University of Mannheim — **Not yet recruiting**
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University of Munich Grosshadern — **Not yet recruiting**
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University of Regensburg — **Not yet recruiting**
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University Medical Center Tuebingen — **Recruiting**
Tuebingen, Germany
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University of Ulm — **Not yet recruiting**
Ulm, Germany
Contact: Thomas Ettrich, MD thomas.ettrich@uniklinik-ulm.de

University Medical Center — **Recruiting**
Wuerzburg, Germany
Contact: Volker Kunzmann, Prof 0049931 201 31042 kunzmann_v@medizin.uni-wuerzburg.de

Sponsors and Collaborators

Universitätsklinikum Hamburg-Eppendorf

Deutsche Krebshilfe e.V., Bonn (Germany)

medac GmbH

Investigators

Principal Investigator: Henning Wege Universitätsklinikum Hamburg-Eppendorf

More Information

No publications provided

Responsible Party:	Universitätsklinikum Hamburg-Eppendorf
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Health Authority:	Germany: Federal Institute for Drugs and Medical Devices

Keywords provided by Universitätsklinikum Hamburg-Eppendorf:

adjuvant chemotherapy	translational research
cholangocarcinoma	multidisciplinary
muscle invasive gall bladder carcinoma	AIO, DGAV, DGVS

Additional relevant MeSH terms:

Carcinoma
Cholangiocarcinoma
Gallbladder Neoplasms
Urinary Bladder Neoplasms
Adenocarcinoma
Biliary Tract Diseases
Biliary Tract Neoplasms
Digestive System Diseases
Digestive System Neoplasms
Gallbladder Diseases
Neoplasms
Neoplasms by Histologic Type
Neoplasms by Site
Neoplasms, Glandular and Epithelial
Urinary Bladder Diseases
Urogenital Neoplasms
Urologic Diseases
Urologic Neoplasms
Cisplatin
Gemcitabine
Anti-Infective Agents
Antimetabolites
Antimetabolites, Antineoplastic
Antineoplastic Agents
Antiviral Agents
Enzyme Inhibitors
Immunologic Factors
Immunosuppressive Agents
Molecular Mechanisms of Pharmacological Action
Pharmacologic Actions

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