KURZPROTOKOLL
NIFE

Öffentlicher Titel	Nal-IRI, 5-Fluorouracil und Leucovorin versus Gemcitabin plus Cisplatin bei fortgeschrittenem Gallenwegskarzinom
Wissenschaftl. Titel	Nal-IRI with 5-fluorouracil (5-FU) and leucovorin or gemcitabine plus cisplatin in advanced biliary-tract cancer - An open label, non-comparative, randomized, multicenter phase II trial
Kurztitel	NIFE
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Verdauung: Gallengangs-/Gallenblasenkrebs (maligne biliäre Tumoren): Erstlinie
Einschlusskriterien	- Written informed consent incl. participation in translational research and any locally-required authorization (EU Data Privacy Directive in the EU) obtained from the subject prior to performing any protocol-related procedures, including screening evaluations - Age >= 18 years at time of study entry - Histologically confirmed, non-resectable, locally advanced or metastatic adenocarcinoma of the intrahepatic or extrahepatic biliary tract - Protocol-specific staging guidelines have to be observed and non-resectability has to be confirmed by local tumor board - Measurable or assessable disease according to RECIST 1.1 - ECOG performance status 0-1 - Life expectancy of more than 3 months - If applicable, adequately treated biliary tract obstruction before study entry with total bilirubin concentration <= 2 x ULN - Adequate blood count, liver-enzymes, and renal function: -White blood cell count >= 3.5 x 10^6/mL; -Platelet count >= 100 x 10^9/L (>100,000 per mm3); -AST (SGOT)/ALT (SGPT) <= 5 x institutional upper limit of normal; -Serum Creatinine <= 1.5 x ULN and a calculated glomerular filtration rate >= 30 mL per minute - Patients not receiving therapeutic anticoagulation must have an INR < 1.5 ULN and PTT < 1.5 ULN within 7 days prior to randomization. The use of full dose anticoagulants is allowed as long as the INR or PTT is within therapeutic limits (according to the medical standard in the institution) and the patient has been on a stable dose for anticoagulants for at least three weeks at the time of randomization - No prior palliative chemotherapy for biliary tract cancer - No adjuvant treatment within 6 months prior to study entry - Subject is willing and able to comply with the protocol for the duration of the study including undergoing treatment and scheduled visits and examinations including follow up
Ausschlusskriterien	- Active uncontrolled infection, chronic infectious diseases, immune deficiency syndromes - Premalignant hematologic disorders, e.g. myelodysplastic syndrome - Clinically significant cardiovascular disease (incl. myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) within 6 months before enrollment - Prior (>5 years) or concurrent malignancy (other than biliary-tract cancer) which either progresses or requires active treatment. Exceptions are: basal cell cancer of the skin, pre-invasive cancer of the cervix, T1a or T1b prostate carcinoma, or superficial bladder tumor [Ta, Tis and T1] - Pre-existing lung disease

- History or clinical evidence of CNS metastases. Exceptions are: Subjects who have completed local therapy and who meet both of the following criteria: (1) are asymptomatic and (2) have no requirement for steroids 6 weeks prior to start of study treatment. Screening with CNS imaging (CT or MRI) is required only if clinically indicated or if the subject has a history of CNS metastases
- History of hypersensitivity to any of the study drugs or any of the constituents of the products
- Allogeneic transplantation requiring immunosuppressive therapy or other major immunosuppressive therapy
- Severe non-healing wounds, ulcers or bone fractions
- Evidence of bleeding diathesis or coagulopathy
- Major surgical procedures, except open biopsy, nor significant traumatic injury within 28 days prior to randomization, or anticipation of the need for major surgical procedure during the course of the study except for surgery of central intravenous line placement for chemotherapy administration
- Medication that is known to interfere with any of the agents applied in the trial
- Female subjects who are pregnant, breast-feeding or male or female patients of reproductive potential who are not employing an effective method of birth control (failure rate of less than 1% per year). [Acceptable methods of contraception are: implants, injectable contraceptives, combined oral contraceptives, intrauterine pessary (only hormonal devices), sexual abstinence or vasectomy of the partner]. Women of childbearing potential must have a negative pregnancy test (serum beta-HCG) at Screening
- Known Gilbert-Meulengracht syndrome
- Known chronic hypoacusis, tinnitus or vertigo
- Any condition or comorbidity that, in the opinion of the investigator, would interfere with evaluation of study treatment or interpretation of patient safety or study results
- Participation in another clinical study with an investigational product during the last 30 days before inclusion or 7 half-lifes of previously used trial medication, whichever is of longer duration
- Previous enrollment or randomization in the present study (does not include screening failure)
- Any other chemotherapy at study start
- Involvement in the planning and/or conduct of the study
- Patient who might be dependent on the sponsor, site or the investigator
- Patient who has been incarcerated or involuntarily institutionalized by court order or by the authorities
- Patients who are unable to consent because they do not understand the nature, significance and implications of the clinical trial and therefore cannot form a rational intention in the light of the facts

Alter 18 Jahre und älter

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Sponsor	AIO-Studien GmbH
Förderer	Baxalta
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03044587 EudraCT 201600246734