ForPatients
by Roche

Biliary Tract CancerCancer

A clinical trial to compare bevacizumab and atezolizumab, cisplatin and gemcitabine with atezolizumab, cisplatin and gemcitabine in people with untreated biliary tract cancer

A Study of Atezolizumab With or Without Bevacizumab in Combination With Cisplatin Plus Gemcitabine in Patients With Untreated, Advanced Biliary Tract Cancer

Trial Status	Trial Runs In	Trial Identifier
Completed	13 Countries	NCT04677504 GO42661

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase II, Randomized, Double-Blind Placebo-Controlled Study of Atezolizumab With or Without Bevacizumab in Combination With Cisplatin Plus Gemcitabine in Patients With Untreated, Advanced Biliary Tract Cancer

Trial Summary:

This study will evaluate the efficacy and safety of atezolizumab with bevacizumab in combination with cisplatin and gemcitabine(CisGem), compared with atezolizumab in combination with CisGem, in participants with advanced biliary tract cancer (BTC) who have not received prior systemic therapy. Treatment will consist of a chemotherapy combination phase followed by a cancer immunotherapy (CIT)/placebo phase.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT04677504 GO42661
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

How does the GO42661 clinical trial work?

This clinical trial is recruiting people who have a type of disease called biliary tract cancer (BTC). In order to take part, patients must have BTC that is either inoperable, metastatic (has spread to other parts of the body) or recurrent (has come back after a period of time when it was not detectable).

The purpose of this clinical trial is to compare the effects, good or bad, of bevacizumab plus atezolizumab, cisplatin and gemcitabine versus atezolizumab, cisplatin and gemcitabine alone on patients with untreated BTC. In this clinical trial, you will get either bevacizumab plus atezolizumab, cisplatin and gemcitabine or placebo plus atezolizumab, cisplatin and gemcitabine.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be at least 18 years old and have been diagnosed with BTC that has either come back after a period of time where it was not detectable, that has spread within the abdomen or that has spread to other parts of the body. If you have hepatitis B infection you must take suitable anti-viral medication in order to take part.

You must not have BTC that is a mix of two different types of cancer (e.g. cholangiocarcinoma and hepatocellular carcinoma) and you must not have previously had systemic treatment for advanced BTC. If you have previously received certain treatments or have certain medical conditions you may not be able to take part.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial?

Everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin) and given either:

- Group A
    - Cycle 1–8: Bevacizumab (as an infusion into the vein on Day 1 of every three-week cycle), atezolizumab (as an infusion into the vein on Day 1 of every three-week cycle), cisplatin and gemcitabine (as infusions into the vein on Day 1 and Day 8 of every three-week cycle)
    - Cycle 9 onwards: Bevacizumab (as an infusion into the vein on Day 1 of every three-week cycle), atezolizumab (as an infusion into the vein on Day 1 of every three-week cycle)
- OR Group B
    - Cycle 1–8: placebo (as an infusion into the vein on Day 1 of every three-week cycle), atezolizumab (as an infusion into the vein on Day 1 of every three-week cycle), cisplatin and gemcitabine (as infusions into the vein on Day 1 and Day 8 of every three-week cycle)
    - Cycle 9 onwards: placebo (as an infusion into the vein on Day 1 of every three-week cycle), atezolizumab (as an infusion into the vein on Day 1 of every three-week cycle)

You will have a 1 in 2 chance of being placed in either group.

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given medicine with no active ingredients (also known as a ‘placebo’) instead of bevacizumab. A placebo is used to show that the doctor or the patients do not sway the results of the clinical trial.

Neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor can find out which group you are in, if your safety is at risk.

How often will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatment bevacizumab/placebo plus atezolizumab, cisplatin and gemcitabine for as long as it can help you. You are free to stop this treatment at any time.

While being given treatment, you will still be seen regularly by the clinical trial doctor. This will include scans every nine weeks to check how you are responding to treatment. After you have your final dose of treatment, your clinical trial doctor will follow up with you about every three months as long as you agree to this.

What happens if I am unable to take part in this clinical trial?

If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04677504

Trial-identifier: **NCT04677504**

Inclusion Criteria:

- Considered to be eligible to receive platinum-based chemotherapy, in the investigator's judgment
- Documentation of recurrent/metastatic or locally advanced unresectable disease based on computed tomography (CT) or magnetic resonance imaging (MRI) scans
- Histologically or cytologically confirmed diagnosis of iCCA, eCCA, or GBC
- No prior systemic therapy for advanced BTC
- At least one measurable untreated lesion (per RECIST v1.1)
- Adequate biliary drainage with no evidence of ongoing infection
- Eastern Cooperative Oncology Group Performance Status of 0 or 1
- Life expectancy of > 3 months
- Adequate hematologic and end-organ function
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods, and agreement to refrain from donating eggs
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agreement to refrain from donating sperm

Exclusion Criteria:

- Recurrent disease <=6 months after curative surgery or <= 6 months after the completion of adjuvant therapy
- Prior local regional therapy such as radioembolization
- Combined or mixed hepatocellular/cholangiocarcinoma
- Clinically significant hepatic encephalopathy within the 12 months prior to Day 1 of Cycle 1
- National Cancer Institute Common Terminoogy Criteria for Adverse Events Grade >= 2 peripheral neuropathy
- Prior bleeding event due to untreated or incompletely treated esophageal and/or gastric varices within 6 months prior to Day 1 of Cycle 1
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 5 months after the final dose of atezolizumab or within 6 months after the final dose of bevacizumab, cisplatin or gemcitabine
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography scan
- History of malignancy other than BTC within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death
- Symptomatic, untreated, or actively progressing CNS metastases

- For patients with lung metastases, if one of the following criteria applies: Large, centrally located pulmonary metastases; Clear tumor infiltration into the thoracic great vessels seen on imaging; Clear cavitation of pulmonary lesions seen on imaging
- Active tuberculosis
- Co-infection with HBV and HCV
- Treatment with systemic immunostimulatory agents or immunosuppressive medication
- Inadequately controlled arterial hypertension
- History of hypertensive crisis or hypertensive encephalopathy
- Significant vascular disease
- Evidence of bleeding diathesis or significant coagulopathy
- Serious, non-healing or dehiscing wound, active ulcer, or untreated bone fracture
- Chronic daily treatment with a non-steroidal anti-inflammatory drug (NSAID)
- Preexisting renal impairment, myelosuppression, or hearing impairment