Olaparib With or Without Durvalumab for DDR Gene Mutated Biliary Tract Cancer Following Platinum-based Chemotherapy

NCT05222971

Status	RECRUITING
Phase	Phase 2
Sponsor	Asan Medical Center
Enrollment	62 participants

Key Eligibility Criteria

Inclusion (15)

- Capable of giving signed informed consent which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol.
- Age 19 years and older
- Eastern Cooperative Oncology Group (ECOG) performance status 0 \~ 1
- Patients must have a life expectancy e 16 weeks.
- Histologically confirmed adenocarcinoma of biliary tract (intrahepatic, extrahepatic cholangiocarcinoma, or gallbladder carcinoma).

... and 10 more (see full listing online)

Exclusion (24)

- Participation in another clinical study with an investigational product during the last 6 months.
- Concurrent enrolment in another clinical study, unless it is an observational (non-interventional) clinical study or during the follow-up period of an interventional study.
- Medical or psychiatric conditions that compromise the patient's ability to give informed consent or to complete the protocol or a history of non-compliance
- Concomitant use of known strong CYP3A inhibitors (eg. itraconazole, telithromycin, clarithromycin, protease inhibitors boosted with ritonavir or cobicistat, indinavir, saquinavir, nelfinavir, boceprevir, telaprevir) or moderate CYP3A inhibitors (eg. ciprofloxacin, erythromycin, diltiazem, fluconazole, verapamil). The required washout period prior to starting study treatment is 2 weeks.
- Concomitant use of known strong (eg. phenobarbital, enzalutamide, phenytoin, rifampicin, rifabutin, rifapentine, carbamazepine, nevirapine and St John's Wort) or moderate CYP3A inducers (eg. bosentan, efavirenz, modafinil). The required washout period prior to starting study treatment is 5 weeks for enzalutamide or phenobarbital and 3 weeks for other agents.

... and 19 more (see full listing online)

Locations (1 total)

Asan Medical Center, Seoul, South Korea