Article details

Title of article

FIGHT-302: First-line pemigatinib vs gemcitabine + cisplatin for advanced cholangiocarcinoma with *FGFR2* rearrangements

Authors

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Article URL

https://www.futuremedicine.com/doi/10.2217/fon-2020-0429

Trial registration number

NCT03656536

Target enrollment: 432 patients (currently recruiting)

Study start date: December 2018

Study procedures: Radiographic tumor assessments (CT/MRI) are performed at baseline, every 9 weeks (every 3 cycles), starting from cycle 3, and until progression is noted by the central reviewer. Adverse events are graded and recorded per the National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0. Quality of life is assessed at regular intervals throughout the study

Objectives/rationale

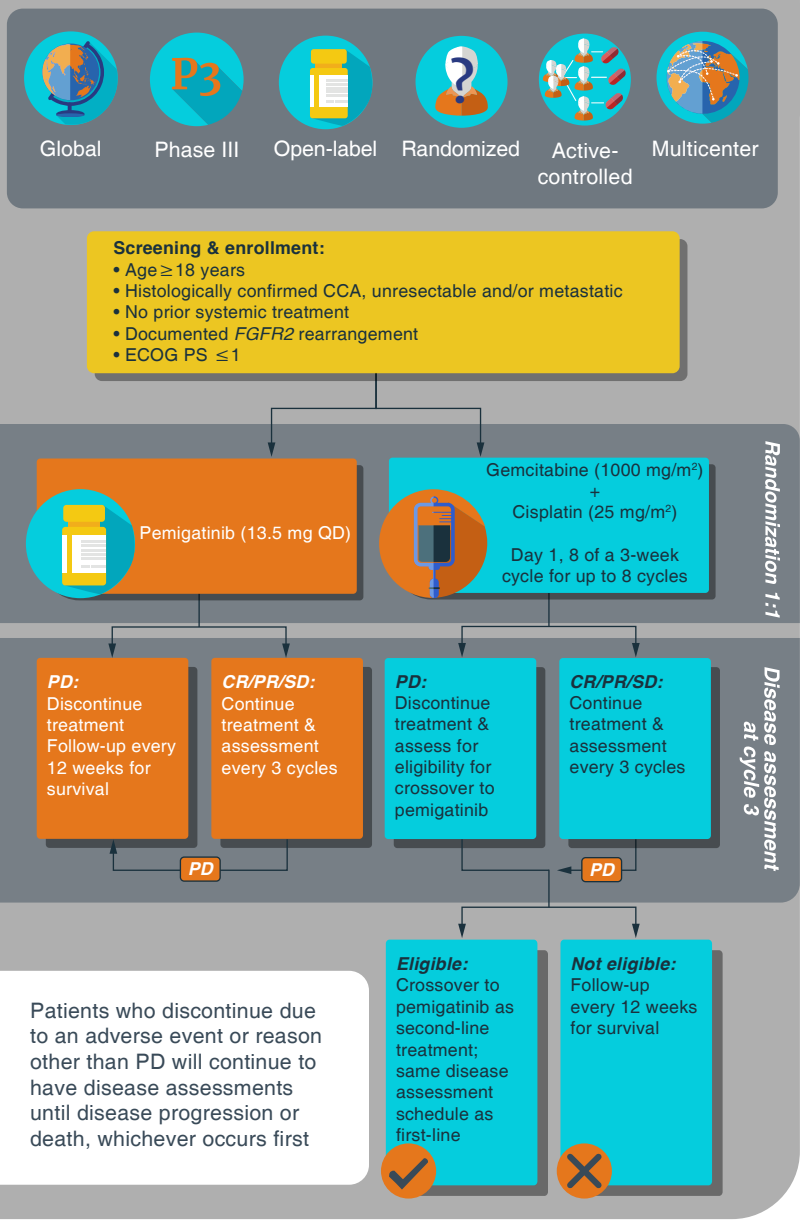
Primary objective

Evaluate the efficacy of pemigatinib versus gemcitabine plus cisplatin in the first-line treatment of patients with cholangiocarcinoma with *FGFR2* rearrangements

Secondary key objectives

Further evaluate the efficacy, safety and tolerability of pemigatinib and the impact of treatment on health-related quality of life

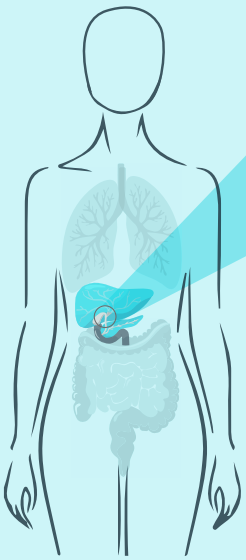
Study design and treatment



Patients who discontinue due to an adverse event or reason other than PD will continue to have disease assessments until disease progression or death, whichever occurs first

Key eligibility criteria

Inclusion



- 18+ — Men and women aged 18 years or older
- Histologically confirmed cholangiocarcinoma that is previously untreated and considered unresectable and/or metastatic
- Radiographically measurable or evaluable disease by CT or MRI per RECIST v1.1
- Documented *FGFR2* rearrangement
- ≤1 — ECOG performance status ≤1

Exclusion

- Corneal/retinal disorders
- Abnormal calcium-phosphate homeostasis

Outcome measures/endpoints

Primary endpoint
PFS

Secondary endpoints:
ORR, OS, DOR, DCR, safety and tolerability, and health-related quality of life

Glossary

CCA: Cholangiocarcinoma; CR: Complete response; CT: Computed tomography; DCR: Disease control rate; DOR: Duration of response; ECOG: Eastern Cooperative Oncology Group; MRI: Magnetic resonance imaging; ORR: Objective response rate; OS: Overall survival; PD: Progressive disease; PFS: Progression-free survival; PR: Partial response; QD: Once daily; RECIST: Response Evaluation Criteria in Solid Tumors; SD: Stable disease