Eligibility criteria
- Histologically or cytologically confirmed unresectable and/or metastatic cholangiocarcinoma
- No prior systemic treatment
- Documented FGFR2 rearrangement
- Evaluable disease by CT or MRI
- ECOG status 0 to 1

N = 432:1:1

Experimental
Pemigatinib

PD: Discontinue therapy
CR/PR/SD: Continue therapy; assess every 3 cycles

Active comparator
Gemcitabine + cisplatin

PD: Discontinue therapy; assess for crossover
CR/PR/SD: Continue therapy

End Points
Primary
- PFS
Select secondary
- ORR
- OS
- DOR
- DCR
- TEAE
- QoL

CR, complete response; DCR, disease control rate; DOR, duration of response; FGFR2, fibroblast growth factor receptor 2; ORR, overall response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PR, partial response; QoL, quality of life; SD, stable disease; TEAE, treatment-emergent adverse effects.