

LBA21

Adjuvant chemotherapy with gemcitabine and cisplatin compared to standard of care after curative intent resection of cholangiocarcinoma and gallbladder carcinoma (ACTICCA-1 trial)

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Background

Despite surgery and adjuvant capecitabine, about 50% of biliary tract cancer (BTC) patients recur or die within two years. Gemcitabine and cisplatin (GC) has been the established chemotherapy regimen in advanced BTC, providing a strong rationale for its evaluation in the adjuvant setting.

Methods

ACTICCA-1 is a randomized, phase III investigator-initiated trial. Patients were enrolled at 60 sites across 7 countries between September 2017 and January 2023 and randomized to adjuvant GC (arm A) or capecitabine (arm B), both for 24 weeks. The primary endpoint is disease-free survival (DFS) in the full analysis set (FAS). Secondary endpoints include overall survival, safety and tolerability of chemotherapy, quality of life, and patterns of disease recurrence.

Results

At the data cut-off date of Dec 31, 2025, 591 patients had been randomized. Median follow-up was 4.8 years. Median age was 63, 46.9% were female, and median interval between surgery and enrolment was 67 days. The location was intrahepatic in 28.3%, perihilar in 19%, distal in 36.5%, and gallbladder in 16.2%. N+ was 47.9%. DFS favoured arm A compared to arm B (median 2.14 vs. 1.49 years, log rank $p=0.097$). As pre-defined in the statistical analysis plan (SAP), due to violation of the proportional hazard assumption Cox model (HR 0.82, 95% CI 0.67-1.01) was not feasible and restricted mean survival time (RMST) was analysed. Patients in arm A experienced on average 2.6 additional DFS months compared to arm B (RMST in the first 3 years $p=0.01$) and a strong trend in overall survival ($p=0.076$). Toxicity showed a slightly higher rate of severe adverse events (130 vs. 113 with 51 vs. 47 treatment related) and adverse events rate (74.4% vs. 69.5% of patients) in arm A compared to B. Further endpoints will be displayed at the meeting.

Conclusions

GC is an adjuvant treatment option for BTC.

Clinical trial identification

NCT02104882; 2012-005078-70.

Legal entity responsible for the study

University Medical Center Hamburg Eppendorf.

Funding

The trial was funded by German Cancer Aid, Cancer Research UK, Dutch Cancer Foundation, Cancer Australia, GONO and a grant for trial medication by Medac.

Disclosure

All authors have declared no conflicts of interest.

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