

# Dynamic Prediction Model for Patients with Unresectable Biliary Malignancies Receiving Systemic Chemotherapy Combined with Immunotherapy: a Multicenter, Observational Study

NCT06849193

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Status	RECRUITING
Sponsor	Zhongda Hospital
Enrollment	332 participants

## Key Eligibility Criteria

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### Inclusion (4)

- 1. Confirmed by histopathological diagnosis and/or clinical diagnosis (typical imaging features, clinical manifestations, laboratory examination, etc.) as biliary malignancy (Chinese Society of Clinical Oncology (CSCO) Guidelines for Diagnosis and Treatment of Biliary malignancy (2024));
- 2. Based on unresectable malignant tumor in the diagnosis of biliary and in patients undergoing chemotherapy with immunosuppressant therapy system;
- 3. The liver function class for Child - Pugh, A or B;
- 4. More than 18 years of age, gender not limited;
- 5. Expected survival time for 3 months or more;
- 6. ECOG PS score 2 or less;
- 7. Meet the following laboratory test parameters:
  - Hematological system function: Absolute neutrophil count  $\geq 1.0 \times 10^9/L$ ; platelet count  $\geq 50 \times 10^9/L$ ; hemoglobin  $\geq 90$  g/L; international normalized ratio less than 1.7 or prothrombin time prolongation not exceeding 4 seconds.
  - Liver function: Alanine aminotransferase/aspartate aminotransferase not exceeding 5 times the upper limit of normal; total bilirubin  $\leq 2.0$  mg/dL [ $\leq 2.38$  mg/dL]; albumin  $\geq 28$  g/L.
  - Renal function: Serum creatinine not exceeding 1.5 times the upper limit of normal.

### Exclusion (9)

- Malignant tumors other than BTC;
- Moderate to severe ascites (ascites reaching a Child-Pugh score of 3);
- Any local treatment (including transcatheter interventional therapy, ablation therapy, internal/external radiotherapy, etc.) or surgical resection or traditional Chinese medicine within 4 weeks before the combination of systemic chemotherapy and immunotherapy;
- Incomplete data, such as incomplete laboratory test data, missing or poor-quality imaging data, or lack of prognostic information;
- Severe liver dysfunction, such as decompensated cirrhosis and other liver diseases that significantly affect bilirubin levels;
- ... and 4 more (see full listing online)

## Locations (2 total)

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Zhongda Hospital,, Nanjing, Jiangsu, China  
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<https://clinicaltrials.gov/study/NCT06849193>

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