Gemcitabine plus cisplatin

NHS Lancashire and South Cumbria Cancer Alliance

Indication

Histologically confirmed unresectable, locally advanced, or metastatic adenocarcinoma of the biliary tract, including intrahepatic or extrahepatic cholangiocarcinoma and gallbladder carcinoma based on ABC01 trial.

Regimen details

Gemcitabine (1000mg/m^2) and cisplatin (25mg/m^2), administered on days 1 and 8 of each cycle.

Table 1 – Treatment regimen details

DRUG	DOSE	DILUENT	ROUTE	FREQUENCY/DURATION
Cisplatin	25mg/m^2	500ml 0.9% sodium chloride	intravenous infusion over 1 hour	Day 1, 8
Gemcitabine	1000mg/m^2	250ml 0.9% sodium chloride	intravenous infusion over 1 hour	Day 1, 8

Cycle frequency

Treatment on day 1 and day 8 of each 21 day cycle.

Number of cycles

8 cycles of combination chemotherapy until disease progression or unacceptable toxicity.

Administration

Intravenous infusion as stated above.

Pre-medication

As per anti-emetic guideline

Emetogenicity – consult anti-emetic policy for full details

High Risk (Category A)

Additional supportive medication

None Specific

Investigations – pre first cycle

Table 2 - Standard Investigations prior to first cycle

Investigation	Validity period
FBC	14 days
U+E (including creatinine)	14 days
LFT	14 days
Mg	14 days
Ca	14 days

Investigations –pre subsequent cycles

FBC, U+E (including creatinine), LFT, Mg Ca

Standard limits for administration to go ahead

If blood results not within range, authorisation to administer **must** be given by prescriber/ consultant.

Table 3 – Standard test result limits for each administration to go ahead and Dose modifications.

Day 1:
Neutrophils ≥ 1
Platelets ≥ 100
Creatinine clearance ≥ 50
Bilirubin ≤ 1.5x ULN

Renal Impairment:
Mild to moderate (CrCl >30-50 mL/min): Omit Cisplatin and consider switching to carboplatin ACU2.
Severe (CrCl <30 mL/min): Pharmacokinetics unknown. Consider dose reduction gemcitabine

Liver Impairment:
Bilirubin > 1.5xULN (30 – 55umol/L) dose reduce gemcitabine to 800mg/m2
>55umol/L for consultant decision

Infusion-Related Reactions:
Grade1 or 2: Interrupt or slow infusion rate
Grade 3 or 4: Permanently discontinue.

Adverse Effects- for full details consult product literature/ reference texts
Anaemia
Nausea
Constipation
Neutropenia

References

1. Durvalumab with gemcitabine and cisplatin for treating unresectable or advanced biliary tract cancer [ID4031] - https://www.nice.org.uk/guidance/indevelopment/gid-ta10920 (accessed 11/12/23)
2. Durvalumab plus Gemcitabine and Cisplatin in Advanced Biliary Tract Cancer. Published June 1, 2022 NEJM Evid 2022;1(8)
3. J. W. Valle et al ABC-01 Trial Gemcitabine with or without cisplatin in patients (pts) with advanced or metastatic biliary tract cancer (ABC): Results of a multicenter, randomized phase III trial (the UK ABC-02 trial). J Clin Oncol 27:15s, 2009 (suppl; abstr 4503)
4. Lamarca A. Benafif S. Ross P. et al. Cisplatin and gemcitabine in patients with advanced biliary tract cancer (ABC) and persistent jaundice despite optimal stenting: effective intervention in patients with luminal disease. Eur J Cancer. 2015; 51: 1694-1703