Systemic Anti Cancer Treatment Protocol

Gemcitabine-Cisplatin

Repeated every 21 days for 8 cycles

PROTOCOL REF: MPHAGEMCIS
(Version No: 1.0)

Approved for use in

Treatment of advanced cholangiocarcinoma / gall bladder carcinoma.

PS 0-1 with adequate renal function.

Dosage

Drug	Dose	Route	Frequency
Cisplatin	25mg/ m^2	IV	Days 1 & 8 of 21 day cycle
Gemcitabine	1000mg/ m^2	IV	Days 1 & 8 of 21 day cycle

Supportive Treatments:

Dexamethasone 4mg BD for 3 days

Domperidone 10mg TDS PRN

Extravasation risk

Gemcitabine

NEUTRAL – no action necessary

Cisplatin

EXFOLIANT – use heat and compression, consider hyaluronidase

Administration

Day	Drug	Dose	Route	Diluent and rate
1 and 8	**Ondansetron** 30mins before chemotherapy	**16mg**	**PO**	
	Dexamethasone 30mins before chemotherapy	**8mg**	**PO**	
	Cisplatin	**25mg/m^2**	**IV**	**1000ml Sodium Chloride 0.9% over 60 minutes**
	Gemcitabine	**1000mg/m^2**	**IV**	**250ml Sodium Chloride 0.9% over 30 minutes**

Main Toxicities

Gemcitabine

Nausea, vomiting, fatigue, diarrhoea, constipation, alopecia, peripheral oedema, rash, influenza-like symptoms, dizziness during infusion, peripheral neuropathy, stomatitis.

Neutropenia, thrombocytopenia, anaemia, elevated liver function tests, haematuria and proteinuria.

Cisplatin

Nausea, vomiting, taste disturbances, peripheral neuropathy, ototoxicity, nephrotoxicity.

Neutropenia, thrombocytopenia, anaemia, hyperuricaemia.

Investigations and Treatment Plan

	Pre	C1 D1	C1 D8	C2 D1	C2 D8	Ongoing
Medical Assessment	X	X		X		For palliative, alternate cycles.
Nursing Assessment	X	X	X	X	X	Every cycle
FBC	X	X	X	X	X	Every cycle
U&E & LFT	X	X	X	X	X	Repeat if clinically indicated
Random blood glucose	X	X		X		Every cycle
CA19.9	X	X		X		Every cycle
Magnesium	X	X		X		Every cycle
CT scan	X					Every 12 weeks
Informed Consent	X					
Blood	X					Repeat if clinically indicated

pressure*						
PS recorded	X	X	X	X	X	Every cycle
Toxicities documented	X	X	X	X	X	Every cycle
Weight recorded	X	X	X	X	X	Every cycle

Dose Modifications and Toxicity Management

Haematological Toxicity

Day	FBC			Treatment Delay
	ANC	AND/ OR	PLT	
1	≥ 1.0		≥ 75	Proceed with treatment
	< 1.0		< 75	Delay treatment until counts recovered
8	≥ 1.0		≥ 75	Proceed with treatment
	0.5 - 0.9		50 - 74	Discuss with clinician. Dose reduce by 25%
	< 0.5		< 50	OMIT

Non-haematological Toxicity

Stomatitis or Diarrhoea Toxicity (CTC Grade)	Treatment Delay	Dose Reduction
Grade 1	No delay	No reduction
Grade 2	Delay until Grade 1 or better	No reduction
Grade 3		Resume at 75%
Grade 4		Resume at 50%

Hepatic impairment

Gemcitabine
No safety data in patients with hepatic impairment. If bilirubin > 27µmol/L, consider reducing dose to 800mg/m^2.
Cisplatin
Renally excreted. No dose adjustments necessary.

Renal impairment

Gemcitabine
No safety data in patients with CrCl < 30ml/min. Consider dose reduction (clinical decision).
Cisplatin
Cisplatin in nephrotoxic. Adequate renal function is required prior to commencing treatment. Proceed if CrCl > 50ml/min. Consider reducing dose by 25% if CrCl 41-50ml/min (discuss with clinician). Contra-indicated if CrCl < 40ml/min. Consider switching to Carboplatin.

References:

Valle J et al; Cisplatin plus Gemcitabine versus Gemcitabine for Biliary Tract Cancer. N Engl J Med 2010; 362: 1273-1281

Gemcitabine 100mg/ml Concentrate for solution for infusion. Summary of Product Characteristics. Accord Healthcare Ltd Middlesex, 06/06/2012. Available from www.medicines.org.uk/emc/medicine last updated 01/11/2012.

Cisplatin 1mg/ml Concentrate for solution for infusion. Summary of Product Characteristics. Accord Healthcare Ltd Middlesex, 21/06/2010. Available from www.medicines.org.uk/emc/medicine last updated 09/01/2015.

Dosage Adjustment for Cytotoxics in Renal and Hepatic Impairment. University College London Hospital NHS Foundation Trust January 2009.

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