Systemic Anti Cancer Therapy Protocol

Gemcitabine
Pancreatic Cancer and Cholangiocarcinoma

PROTOCOL REF: MPHAHPBGEM
(Version No: 2.0)

Approved for use in

First line adjuvant treatment for resected adenocarcinoma of pancreas.

Treatment of locally advanced or metastatic adenocarcinoma of pancreas or cholangiocarcinoma.

Dosage

Drug	Dose	Route	Frequency
Gemcitabine	1000mg/m^2	IV	Days 1, 8 and 15 of 28 day cycle

Given for 6 cycles in adjuvant setting

Continue until disease progression in advanced setting

Supportive Treatments:

Domperidone 10mg tablets to be taken three times a day when required

Thromboprophylaxis:

In line with recent NICE recommendations, patients with pancreatic cancer receiving chemotherapy should receive thromboprophylaxis with a LMWH unless contra-indicated. Contra-indications include high bleeding-risk. The decision regarding thromboprophylaxis as part of chemotherapy has to be clearly documented by the consultant.

- Dalteparin 5000 IU by subcutaneous injection once daily

Extravasation risk

Gemcitabine

NEUTRAL – no action necessary

Refer to Clatterbridge Policy 'Prevention and Management of Extravasation Injuries' for further guidance.

Administration

Day	Drug	Dose	Route	Diluent and rate
1	**Dexamethasone** 30mins before chemotherapy	**8mg**	PO	
	Gemcitabine	**1000mg/m^2**	IV	250ml Sodium Chloride 0.9% over 30 minutes
8	**Dexamethasone** 30mins before chemotherapy	**8mg**	PO	
	Gemcitabine	**1000mg/m^2**	IV	250ml Sodium Chloride 0.9% over 30 minutes
15	**Dexamethasone** 30mins before chemotherapy	**8mg**	PO	
	Gemcitabine	**1000mg/m^2**	IV	250ml Sodium Chloride 0.9% over 30 minutes
22	**NO TREATMENT**			

Drug Interactions:

Warfarin/coumarin anti-coagulants – can increase anticoagulant effect or cause fluctuations. Avoid if possible or consider switching patient to a LMWH during treatment. If patient continues to take an oral anticoagulant, INR must be checked at least once a week and dose adjusted accordingly.

Gemcitabine is a radio-sensitiser.

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

Investigations and Treatment Plan

	Pre	C1 D1	C1 D8	C1 D15	C2 D1	C2 D8	C2 D15	Ongoing
Clinical Assessment	X	X			X			For palliative, alternate cycles.
SACT Assessment	X	X	X	X	X	X	X	Every cycle
FBC	X	X	X	X	X	X	X	Every cycle
U&E & LFT	X	X	X	X	X	X	X	Repeat if clinically indicated
Magnesium	X	X			X			Every cycle
Random blood glucose	X	X			X			Every cycle
CA19.9	X	X			X			Every cycle
CT scan	X							Every 12 weeks
Informed Consent	X							
Blood pressure*	X							Repeat if clinically indicated
PS recorded	X	X	X	X	X	X	X	Every cycle
Toxicities documented	X	X	X	X	X	X	X	Every cycle
Weight recorded	X	X	X	X	X	X	X	Every cycle
Height recorded	X							

Dose Modifications and Toxicity Management

Haematological Toxicity

Day	FBC			Treatment Delay
	ANC ($x10^9$/L)	AND/ OR	PLT ($x10^9$/L)	
Day 1	≥ 1.0		≥ 75	Proceed with treatment
	< 1.0		< 75	Delay treatment until counts recovered
Day 8	≥ 1.0		≥ 75	Proceed with treatment
	0.5 - 0.9		50 - 74	Discuss with clinician. Dose reduce by 25%
	< 0.5		< 50	OMIT
Day 15	≥ 1.0		≥ 75	Proceed with treatment
	0.5 - 0.9		50 - 74	Discuss with clinician. Dose reduce by 25%
	< 0.5		< 50	OMIT

If day 1 is deferred or days 8 or 15 are reduced/omitted on more than two occasions, discuss with clinician and consider an overall dose reduction by 20-25%.

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.

Renal impairment

Gemcitabine
No safety data in patients with CrCl < 30ml/min. Consider dose reduction (clinical decision).

References:

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

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

3. Cancer Chemotherapy: Guidelines for the administration of chemotherapy and the nursing care of cancer patients (6th Edition)

4. NICE guideline NG89. Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism (August 2019).