

BCCA Protocol Summary for Treatment of Locoregionally Recurrent and/or Metastatic Nasopharyngeal Cancer with CISplatin and Gemcitabine

Protocol Code: *HNNAVPG*

Tumour Group: *Head and Neck*

Contact Physician: *Dr. Cheryl Ho*

ELIGIBILITY:

- Locoregionally recurrent and/or metastatic nasopharyngeal cancer not amenable to curative local therapy. Preferably no prior CISplatin exposure – at least for locoregionally recurrent/metastatic disease
- A “Class II Drug Registration Form” for gemcitabine must be completed at the time of initiation of treatment. For other indications, an “Individual Use of Benefit Drug List Medication for an Undesignated Indication” form must be approved.

EXCLUSIONS:

- contraindication to CISplatin (e.g. deafness, intolerance to fluid load, neuropathy)
- ECOG status greater than or equal to 3

TESTS:

- Baseline: CBC & differential, platelets, creatinine, liver function tests, bilirubin
- Before each treatment:
 - Day 1 – CBC & differential, platelets, creatinine, liver function tests, bilirubin.
 - Day 8 – CBC & differential, platelets, creatinine.
 - Day 15 – CBC & Differential , platelets

PREMEDICATIONS:

- Antiemetic protocol for highly emetogenic chemotherapy protocols (see protocol SCNAUSEA).
- May consider adding aprepitant 125 mg PO 30 minutes pre-chemotherapy and 80 mg PO once daily in the morning on Days 2 and 3

TREATMENT:

Drug	Dose	BCCA Administration Guideline
(Administer gemcitabine first)		
Gemcitabine	1,000 mg/m ² /day on days 1, 8 and 15 (total dose per cycle = 3,000 mg/m ²)	IV in 250 mL NS over 30 min
CISplatin	50 mg/m ² /day on day 1 and 8	Prehydrate with 1,000 mL NS over 1 hour, then CISplatin IV in 500 mL NS with 10 mEq KCl, 0.5 g magnesium sulfate, over 1 hour

- Repeat every 28 days x 4-6 cycles

DOSE MODIFICATIONS:**1. Hematology:****For gemcitabine day 1 of each cycle**

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose
greater than or equal to 1	and	greater than 100	100%
0.5-0.99	or	75-100	75%
less than 0.5	or	less than 75	Delay*
*CISplatin also delayed			

For gemcitabine day 8 and 15 of each cycle

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose**
greater than or equal to 1	and	greater than 100	100%
0.5-0.99	or	75-100	75%
less than 0.5	or	less than 75	Omit
**Dose adjustment only for the day of treatment the CBC is drawn			

2. Renal Dysfunction:

Calculated Cr Clearance (mL/min)	CISplatin dose	Gemcitabine dose
greater than or equal to 50	100%	100%
less than 50	Hold CISplatin	100%

3. Other Toxicities: for gemcitabine only

Grade	Stomatitis		Diarrhea	Dose
1	Painless ulcers, erythema or mild soreness	and/or	Increase of 2-3 stools/day	100%
2	Painful erythema, edema, or ulcers but can eat	and/or	Increase of 4-6 stools, or nocturnal stools	Omit until toxicity resolved then resume at 100%
3	Painful erythema, edema, or ulcers and cannot eat	and/or	Increase of 7-9 stools per day or incontinence, malabsorption	Omit until toxicity resolved then resume at 75%
4	Mucosal necrosis, requires parenteral support	and/or	Increase of greater than or equal to 10 stools per day or grossly bloody diarrhea requiring parenteral IV support	Omit until toxicity resolved then resume at 50%

PRECAUTIONS:

- Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
- Renal Toxicity:** Nephrotoxicity is common with CISplatin. Encourage oral hydration. Avoid nephrotoxic drugs such as aminoglycoside antibiotics. Irreversible renal failure associated with hemolytic uremic syndrome may occur (rare) with gemcitabine. Use caution with pre-existing renal dysfunction.
- Pulmonary Toxicity:** Acute shortness of breath may occur. Discontinue treatment if drug-induced pneumonitis is suspected.

Call Dr. Cheryl Ho or tumour group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

Date activated: 1 May 2006

Date revised: 01 June 2011 (Infusion section revised)

References:

1. Ngan RK, Yiu HH, Lau WH, et al. Combination gemcitabine and cisplatin chemotherapy for metastatic or recurrent nasopharyngeal carcinoma: report of a phase II study. *Ann Oncol* 2002;13(8):1252-8.