

BCCA Protocol Summary For Treatment of Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck with Cisplatin and Docetaxel

Protocol Code:

UHNAVPD

Tumour Group:

Head and Neck

Contact Physician:

Dr. Cheryl Ho

ELIGIBILITY:

- Recurrent or metastatic squamous cell carcinoma of head and neck including primary unknown
- Adequate hematologic, hepatic and renal function.
- Age greater than or equal to 18 years.
- ECOG performance status 0, 1.
- Protocol **NOT** to be delivered with concurrent radiotherapy.

NOTE: A BCCA "Compassionate Access Program" form with appropriate clinical information for each patient must be submitted and approved prior to treatment.

EXCLUSION:

- ECOG performance status greater than or equal to 2

TESTS:

- Baseline: CBC & differential, platelets, serum creatinine, liver enzymes
 - Before each treatment: CBC & differential, platelets, serum creatinine
 - Before cycle 4 and anytime if clinically indicated*: liver enzymes
- *See precaution #5 for guidelines regarding hepatic function.

PREMEDICATIONS:

- Dexamethasone 8 mg PO bid for 3 days starting one day prior to each administration of docetaxel
- A minimum of 3 doses of dexamethasone pre-treatment are required
- Antiemetic protocol for Highly emetogenic chemotherapy (see protocol SCNAUSEA).
- Docetaxel-induced onycholysis and cutaneous toxicity of the hands may be prevented by wearing frozen gloves starting 15 minutes before docetaxel infusion until 15 minutes after end of docetaxel infusion; gloves should be changed after 45 minutes of wearing to ensure they remain cold during the entire docetaxel infusion.

TREATMENT:

Drug	Dose	BCCA Administration Guideline
Cisplatin	75 mg/m ²	Prehydrate with 1000 mL NS over 1 hour, then Cisplatin IV in 500 mL NS with 20 mEq KCl, 1 g magnesium sulfate, 30 g mannitol over 1 hour
Docetaxel	75 mg/m ²	IV in 250 mL* NS or D5W over 1 hour (use non-PVC equipment)

*If 75-185 mg, use 250 mL bag. If greater than 185 mg, use 500 mL bag.

- Repeat every 21 days x 4-6 cycles

DOSE MODIFICATIONS:1. **Hematology** (for Docetaxel)

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose*
greater than or equal to 1.5	and	greater than 100	100%
1-1.49	Or	75-100	75%
less than 1	Or	less than 75	Delay
*Consider decreasing docetaxel to 75% if an episode of febrile neutropenia occurs with the prior cycle of treatment			

2. **Hepatic dysfunction:** for Docetaxel

Alkaline phosphatase		AST and/or ALT	Dose
less than 2.5 x ULN	and	less than 1.5 x ULN	100%
2.5 - 5 x ULN	and	1.5 - 5 x ULN	75%
greater than 5 x ULN	or	greater than 5 x ULN	Delay*
*Discuss with contact physician			

ULN = upper limit of normal

3. **RENAL DYSFUNCTION:** for Cisplatin

Calculated Cr Clearance (mL/min)	Cisplatin dose
greater than or equal to 60	100%
45-59	80% cisplatin
less than 45	Hold cisplatin or delay with additional IV fluids

PRECAUTIONS:

- Fluid retention:** Dexamethasone premedication must be given to reduce incidence and severity of fluid retention.
- Hypersensitivity** reactions to docetaxel are common but it is not necessary to routinely initiate the infusion slowly. If slow initiation of infusion is needed, start infusion at 30 mL/h x 5 minutes, then 60 mL/h x 5 minutes, then 120 mL/h x 5 minutes, then complete infusion at 250 mL/h (for 500 mL bag, continue 250 mL/h for 5 minutes and then complete infusion at 500 mL/h). Refer to BCCA Hypersensitivity Guidelines.
- Extravasation:** Docetaxel causes pain and tissue necrosis if extravasated. Refer to BCCA Extravasation Guidelines.

4. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
5. **Hepatic Dysfunction:** Docetaxel undergoes hepatic metabolism. Hepatic dysfunction (particularly elevated AST) may lead to increased toxicity and usually requires a dose reduction. Baseline liver enzymes are recommended before cycle 1 and then if clinically indicated (eg, repeat liver enzymes prior to each treatment if liver enzymes are elevated, liver metastases are present or there is severe toxicity such as neutropenia). If liver enzymes are normal and there is no evidence of liver metastases or severe toxicity, check liver enzymes after 3 cycles (i.e., at cycle 4). Note: this information is intended to provide guidance but physicians must use their clinical judgment when making decisions regarding monitoring and dose adjustments.

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

Date activated: 1 Jul 2010

Date revised: 01 June 2011 (Infusion section revised)

REFERENCES:

1. Gedlicka C, Formanek M, Selzer E, et al. Phase II study with docetaxel and cisplatin in the treatment of recurrent and/or metastatic squamous cell carcinoma of the head and neck. *Oncology* 2002;63(2):145-50.
2. Baur M, Kienzer HR, Schweiger J, et al. Docetaxel/cisplatin as first-line chemotherapy in patients with head and neck carcinoma: a phase II trial. *Cancer* 2002;94(11):2953-8.
3. Glisson BS, Murphy BA, Frenette G, et al. Phase II Trial of docetaxel and cisplatin combination chemotherapy in patients with squamous cell carcinoma of the head and neck. *J Clin Oncol* 2002;20(6):1593-9.
4. Caponigro F, Massa E, Manzione L, et al. Docetaxel and cisplatin in locally advanced or metastatic squamous-cell carcinoma of the head and neck: a phase II study of the Southern Italy Cooperative Oncology Group (SICOG). *Ann Oncol* 2001;12(2):199-202.
5. Specht L, Larsen SK, Hansen HS. Phase II study of docetaxel and cisplatin in patients with recurrent or disseminated squamous-cell carcinoma of the head and neck. *Ann Oncol* 2000;11(7):845-9.