BC Cancer Protocol Summary For the Treatment of Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck with Platinum and DOCEtaxel

Protocol Code:	*HNAVPD*
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.
- If there is a contraindication to CISplatin (e.g. deafness, intolerance to fluid overload, neuropathy), consideration should be given to using CARBOplatin.

TESTS:

- Baseline: CBC & differential, platelets, serum creatinine, ALT, Alk Phos, bilirubin, LDH, GGT, albumin
- Before each treatment: CBC & differential, platelets, serum creatinine
- Before cycle 4 and anytime if clinically indicated*: GGT, LDH, bilirubin, ALT, albumin
  *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).
- Antiemetic protocol for Moderately emetogenic chemotherapy with CARBOplatin (see SCNAUSEA protocol).
- 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	BC Cancer Administration Guideline
DOCEtaxel	75 mg/m^2	IV in NS or D5W 250 to 500 mL over 1 hour (use non-DEHP equipment)
CISplatin	75 mg/m^2	Prehydrate with NS 1000 mL over 1 hour, then CISplatin IV in NS 500 mL with potassium chloride 20 mEq, magnesium sulfate 1 g, mannitol 30 g over 1 hour

- Repeat every 21 days x 4 to 6 cycles

Alternatively, CARBOplatin may be used instead of CISplatin:

DRUG	DOSE	BC Cancer Administration Guidelines
CARBOplatin	AUC 5 or 6 DAY 1 only Dose = AUC† x (GFR* + 25)	IV in 100 to 250 mL NS over 30 minutes.

† determined at discretion of the attending medical oncologist.
*GFR preferably from nuclear renogram, if not possible use:

$$GFR = \frac{N \times (140\text{-age in years}) \times wt\ (kg)}{\text{serum creatinine (micromol/L)}}$$ N = 1.04 (women) or 1.23 (men)

The estimated GFR should be capped at 125 mL/min when it is used to calculate the initial CARBOplatin dose. When a nuclear renogram is available, this clearance would take precedence.

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 to 1.49	or	75 to 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		ALT	Dose
less than 2.5 x ULN	**and**	less than 1.5 x ULN	100%
2.5 to 5 x ULN	**and**	1.5 to 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 to 59	80% CISplatin
less than 45	Hold CISplatin or delay with additional IV fluids or go to CARBOplatin option.

PRECAUTIONS:

1. **Fluid retention**: Dexamethasone premedication must be given to reduce incidence and severity of fluid retention.
2. **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 BC Cancer Hypersensitivity Guidelines.
3. **Extravasation**: DOCEtaxel causes pain and tissue necrosis if extravasated. Refer to BC Cancer 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: 1 May 2021 (IV bag size clarified, institution name revised)

REFERENCES:

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6. Samlowski WE, Moon J, Kuebler JP, et al. Evaluation of the combination of docetaxel/carboplatin in patients with metastatic or recurrent squamous cell carcinoma of the head and neck (SCCHN): a Southwest Oncology Group Phase II study. Cancer Invest 2007;25(3):182-8.