

BCCA Protocol Summary for Adjuvant Cisplatin and Vinorelbine Following Resection of Non-Small Cell Lung Cancer

Protocol Code: *LUAJNP*

Tumour Group: *Lung*

Contact Physician: *Dr. Christopher Lee*

ELIGIBILITY:

- Fully resected stage II or IIIA non-small cell lung cancer. Fully resected stage IB non-small cell lung cancer, if considered at high-risk for relapse, but uncertainty of benefit must be discussed with individual patient.
- Lobectomy or pneumonectomy preferred; segmentectomy or wedge resection permitted
- Treatment to start within 60 days of definitive surgery
- ECOG performance status 0 or 1
- Adequate renal function: creatinine clearance greater than 60 mL/min
- Adequate hepatic function: bilirubin less than 35
- Prior to treatment, should consider Pneumococcal vaccine, and influenza vaccine, if appropriate for season

EXCLUSIONS:

- Carboplatin cannot be substituted for Cisplatin; if Cisplatin contraindicated or relatively contraindicated, consider treatment with LUAJPC
- ECOG performance status 2 or higher

TESTS:

- Baseline: CBC & differential, platelets, creatinine, liver function tests, bilirubin
- Before each cycle: CBC & differential, platelets, creatinine
- Before days 8 and 15: CBC & differential, platelets
- If clinically indicated: bilirubin prior to each cycle

PREMEDICATIONS:

- Antiemetic protocol for highly emetogenic chemotherapy (see protocol SCNAUSEA).

TREATMENT:

Drug	Dose	BCCA Administration Guideline
(Drugs can be given in any sequence)		
Cisplatin	80 mg/m ² day 1	IV in 500 mL NS with 20 mEq KCl, 1 g magnesium sulphate, 30 g Mannitol over 1 hour*
Vinorelbine	30 mg/m ² days 1, 8, 15	IV in 50 mL NS over 6 min
*Prehydrate with 1 L NS over 1 hour		

- Repeat every 21 days x 4 cycles

DOSE MODIFICATIONS:**1(a). Hematology: for vinorelbine on day 1**

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose
greater than or equal to 1.5	and	greater than or equal to 100	100%
1.0-1.49	or	75-99	75%
less than 1.0	or	less than 75	Delay* †

*Delay entire cycle

†If day 1 delayed with day 15 of preceding cycle having been delivered, omit vinorelbine on day 15 of upcoming and all subsequent cycles

1(b). Hematology: for vinorelbine on days 8 and 15

ANC (x 10 ⁹ /L)		Platelets (x 10 ⁹ /L)	Dose
greater than or equal to 1.5	and	greater than or equal to 100	100%
1.0-1.49	or	75-99	75%
less than 1.0	or	less than 75	Omit*

*If ANC less than 1.0 and/or platelets less than 100 on day 15, omit vinorelbine on day 15 of all subsequent cycles

2. Hepatic dysfunction: for vinorelbine cycles 2-4

Bilirubin (micromol/L)	Dose
less than 35	100%
greater than or equal to 35	Omit, consider discontinuing therapy

3. Renal dysfunction: for cisplatin

Creatinine clearance (mL/min)	Dose
greater than 60	100%
45-60	75% (same prehydration as 80 mg/m ² dose)*
less than 45	Delay † **

*May consider one 1-week delay with additional hydration
† Delay entire cycle
**Consider switch to LUAJPC protocol for remaining cycles if creatinine clearance does not improve

PRECAUTIONS:

- 1. Extravasation:** Vinorelbine causes pain and tissue necrosis if extravasated. It is recommended to flush thoroughly with 75-100 mL NS after infusing vinorelbine. Hydrocortisone 100 mg IV prior to vinorelbine may be of benefit. Refer to BCCA Extravasation Guidelines.
- 2. Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
- 3. Renal Toxicity:** Nephrotoxicity is common with cisplatin. Encourage oral hydration. Avoid nephrotoxic drugs such as aminoglycoside antibiotics.

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

Date activated: 01 Feb 2005 (Activated as ULUAJNP)

Date revised: 1 June 2011 (Infusion section revised)

REFERENCES:

1. The International Adjuvant Lung Cancer Trial Collaborative Group. Cisplatin-based adjuvant chemotherapy in patients with completely resected non-small-cell lung cancer. *N Engl J Med* 2004; 350: 351-360.
2. Winton T, Livingston R, Johnson D, et al. Vinorelbine plus cisplatin vs. observation in resected non-small-cell lung cancer. *N Engl J Med* 2005;352:2589-97.