BC Cancer 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:

Patients must have:

- Fully resected stage II or IIIA non-small cell lung cancer, or 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

Patients should have:

- Good performance status
- Prior to treatment, should consider Pneumococcal vaccine, and influenza vaccine, if appropriate for season
- Adequate renal function: creatinine clearance greater than or equal to 45 mL/minute
- Adequate hepatic function: total bilirubin less than 35

Note:

 CARBOplatin cannot be substituted for CISplatin; if CISplatin contraindicated or relatively contraindicated, consider treatment with LUAJPC

TESTS:

- Baseline: CBC & Diff, creatinine, alkaline phosphatase, ALT, total bilirubin, LDH
- Before each cycle: CBC & Diff, creatinine
- Before Day 8: CBC & Diff
- If clinically indicated: total bilirubin

PREMEDICATIONS:

Antiemetic protocol for highly emetogenic chemotherapy (see protocol <u>SCNAUSEA</u>).

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline		
CISplatin	75 mg/m ² on Day 1	IV in NS 500 mL with potassium chloride 20 mEq, magnesium sulphate 1 g, Mannitol 30 g over 1 hour*		
vinorelbine	30 mg/m ² on Days 1 and 8	IV in NS 50 mL over 6 min		
*Prehydrate with NS 1000 mL 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 to less than 1.5	or	75 to less than 100	75%	
Less than 1.0	or	Less than 75	Delay*	
*Delay entire cycle				

1(b). Hematology: for vinorelbine on Day 8

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 to less than 1.5	or	75 to less than 100	75%
less than 1.0	or	less than 75	Omit

2. Hepatic dysfunction: for vinorelbine

Bilirubin (micromol/L)	Dose
less than or equal to 35	100%
36 to 50	50%
greater than 50	25%

3. Renal dysfunction: for CISplatin

Creatinine clearance (mL/min)	Dose	
greater than or equal to 60	100%	
45 to less than 60	75% (same prehydration as 75 mg/m² dose)*	
less than 45	Delay [†] **	
*May consider one 1-week delay with additional hydration		

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† Delay entire cycle

PRECAUTIONS:

- 1. **Extravasation**: Vinorelbine causes pain and tissue necrosis if extravasated. It is recommended to flush thoroughly with NS 75 to 100 mL after infusing vinorelbine. Hydrocortisone IV 100 mg prior to vinorelbine may be of benefit. Refer to BC Cancer Extravasation Guidelines.
- 2. **Neutropenia**: Fever or other evidence of infection must be assessed promptly and treated aggressively. Refer to BC Cancer Febrile Neutropenia Guidelines.
- 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.

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.

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Activated: 1 Feb 2005 (as ULUAJNP) Revised: 1 Mar 2025 (Eligibility, treatment dose modifications and precautions updated, exclusions removed)

^{**}Consider switch to LUAJPC protocol for remaining cycles if creatinine clearance does not improve