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:

- 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 or equal to 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, alkaline phosphatase, ALT, total bilirubin, LDH
- 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).

Activated: 1 Feb 2005 (as ULUAJNP) Revised: 1 July 2018 (LFTs, dose mods, BC Cancer)

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
(Drugs can be given in any sequence)		
CISplatin	80 mg/m^2 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 days 1, 8, 15	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 †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 to less than 1.5	or	75 to less than 100	75%
less than 1.0	or	less than 75	Omit*
*If ANC less than 1 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 to 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 or equal to 60	100%
45 to less than 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 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.
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.